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Howard W. Brill

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## PROTECTION FOR THE HARD OF HEARING: STATE AND FEDERAL REGULATION OF HEARING AID DEALERS

Howard W. Brill\*

*Nearly three million Americans have come to rely on hearing aids for assistance with their hearing problems. In this Article, Professor Brill compares the forty-five state laws and the new federal guidelines which regulate the hearing aid industry in an attempt to determine which state regulations are most effective in meeting the desired goal of protecting the hard of hearing.*

Fifteen million Americans are handicapped by hearing losses.<sup>1</sup> Since the development of the first wearable electronic hearing aids in the mid-1930's,<sup>2</sup> three million individuals have come to rely on the hearing aid for assistance with their handicap. Each year 15,000 dealers distribute 600,000 hearing aids to the public.<sup>3</sup> Because of a concern that many individuals were purchasing aids which were either unnecessary or of negligible assistance, or that persons were being taken advantage of by unqualified or unscrupulous dealers, state legislatures have enacted statutes designed to provide some protection for those handicapped citizens.<sup>4</sup> The first statute<sup>5</sup> was enacted by Oregon in 1959. Similar statutes were passed by forty-four other

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\* Associate Professor of Law, University of Arkansas. B.A. Duke University; J.D. University of Florida.

1. STAFF STUDY, STATE LICENSING LAWS AND TRAINING REQUIREMENTS FOR HEARING AID DEALERS, PERMANENT SUBCOMMITTEE ON INVESTIGATIONS, COMMITTEE ON GOVERNMENT OPERATIONS, United States Senate, 94th Cong., 1st Sess. 1 (1975) [hereinafter cited as STAFF STUDY].

2. L. WATSON & T. TOLAN, HEARING TESTS AND HEARING INSTRUMENTS 270-83 (1949). For an illustrated history of the hearing aid covering 25 centuries and including Holmes, Beethoven, Alexander Graham Bell (in some ways the father of the modern hearing aid) and discussing carbon, vacuum and transistor aids, see BERGER, THE HEARING AID 7-81 (1970) [hereinafter cited as BERGER].

3. STAFF STUDY, *supra* note 1, at 1; *Hearing Aid Industry*, PERMANENT SUBCOMMITTEE ON INVESTIGATIONS, COMMITTEE ON GOVERNMENT OPERATIONS, United States Senate, 14th Cong., 2d Sess. 152-153 (1976) [hereinafter cited as INVESTIGATIONS]. Those figures, which are only rough estimates, vary according to the source. It also has been estimated that perhaps 75% of the hearing aids dispensed are distributed by 15% of the dealers, and that 80% of the hard of hearing persons could be helped with hearing aids. *Id.* at 85.

4. For a detailed discussion of the abuses involved in the selling and dispensing of hearing aids, see HEARING AIDS AND THE OLDER AMERICAN, SUBCOMMITTEE ON CONSUMER INTERESTS OF THE ELDERLY, SPECIAL COMMITTEE ON AGING, United States Senate, 93rd Cong., 1st Sess. (1973) [hereinafter cited as ELDERLY].

5. The hearing aid licensing approach first was proposed in 1941. For a brief history of the various proposals, see BERGER, *supra* note 2, at 130-33.

states between 1966 and 1976.<sup>6</sup> Building on the state statutes, the Federal Trade Commission and the Food and Drug Administration have proposed federal action in this area.<sup>7</sup>

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6. The statutes, in order of original enactment, are:

- 1959: OR. REV. STAT. § 694.015-.991 (1975).  
 1966: MICH. COMP. LAWS ANN. § 338.1451-.1466 (1976).  
 1967: FLA. STAT. ANN. § 468.120-.138 (West 1977).  
       IND. CODE ANN. § 25-20-1-1 to 24. (Burns 1974) (amended 1976).  
       TENN. CODE ANN. § 63-1501 to 1521 (1976).  
 1968: KAN. STAT. ANN. § 74-5801 to 5824 (1972) (amended 1976).  
       LA. REV. STAT. ANN. § 37:2441-.2465 (West 1974).  
       S.D. COMPILED LAWS ANN. § 36-24-1 to 43 (1972) (amended 1976).  
 1969: ARK. STAT. ANN. § 72-1701 to 1717 (Supp. 1975).  
       MD. ANN. CODE art. 43, §§ 737-754A (1971) (amended 1976).  
       MONT. REV. CODES ANN. § 66-3003 to 3022 (Supp. 1975).  
       NEB. REV. STAT. § 71-4701 to 4719 (1976).  
       N.M. STAT. ANN. § 67-36-1 to 18 (1974).  
       N.C. GEN. STAT. § 93D-1 to 16 (Supp. 1975).  
       N.D. CENT. CODE § 43-33-01 to 19 (Supp. 1977).  
       OHIO REV. CODE ANN. § 4747.01-.99 (Page 1977).  
       TEX. REV. CIV. STAT. ANN. § 4566-1.01 to 1.22 (Vernon 1976).  
       WISC. STAT. ANN. § 459.01-.14 (West 1974) (amended 1976).  
 1970: ARIZ. REV. STAT. § 36-1901 to 1938 (1974).  
       CAL. BUS. & PROF. CODE §§ 3300-3456 (West 1974).  
       GA. CODE ANN. § 84-5601 to 5620 (1975).  
       VA. CODE § 54-524.110-.116 (1976).  
 1971: ALA. CODE, tit. 46, § 150(21)-(39) (Supp. 1974).  
       IDAHO CODE § 54-2901 to 2919 (Supp. 1977).  
       S.C. CODE § 40-25-10 to 190 (1977).  
 1972: CONN. GEN. STAT. ANN. § 20-396 to 407 (West Supp. 1976).  
       KY. REV. STAT. § 334.010-.990 (Supp. 1976).  
       MISS. CODE ANN. § 73-14-1 to -47 (Supp. 1977).  
 1973: DEL. CODE tit. 16, §§ 2001-2020 (1975) (amended 1976).  
       MINN. STAT. ANN. § 145.43-.45 (West Supp. 1976).  
       MO. REV. STAT. § 346.010-.135 (Vernon Supp. 1976).  
       NEV. REV. STAT. § 637A.010-.360 (1975).  
       N.J. STAT. ANN. § 45:9A-1 to-28 (West Supp. 1977).  
       OKLA. STAT. ANN. tit. 59, §§ 1551-1569 (West Supp. 1976).  
       R.I. GEN. LAWS § 5-49-1 to 20 (1976).  
       WASH. REV. CODE ANN. § 18.35.010-.900 (Supp. 1977).  
       W. VA. CODE § 16-24-1 to 20 (Supp. 1976).  
 1974: HAW. REV. STAT. § 451A-1 to 19 (Supp. 1975).  
       IOWA CODE ANN. § 154A.1-.27 (West Supp. 1977).  
 1975: COLO. REV. STAT. § 12-65-101 to 121 (Supp. 1976).  
       ME. REV. STAT. tit. 32, §§ 1658 to 1660-F (Supp. 1976).  
       N.Y. GEN. BUS. LAW §§ 780-787 (McKinney Supp. 1976).  
       VT. STAT. ANN., tit. 18, §§ 4581-4586 (Supp. 1977).  
 1976: PA. STAT. ANN. tit. 35 § 6700-101 to 802 (Purdon Supp. 1977).  
 1977: WYO. SESS. LAWS Ch. 163 (1977).  
       (N.H.) CCH MED. DEVICES. REP. ¶ 17,220 (statute enacted Nov. 1977).

Four state legislatures have not acted in this area: Alaska, Illinois, Massachusetts and Utah.

7. Proposed Federal Trade Commission Rules for the Hearing Aid Industry, 40 Fed. Reg. 26,646 (1975); Food and Drug Administration Regulation for Hearing Aid Devices, 42 Fed. Reg.

The statutes that have been enacted by the state legislatures to control hearing aid dealers fall into three categories. The most common type of statute enacted during the 1960's follows the standard approach to a regulated industry or occupation. It creates a board of hearing aid dealers or fitters which is given the power to license individuals. Licenses are granted following successful completion of an examination. The statute may place limited controls upon the operations and business practices of those licensed hearing aid dealers. The second type of statute, which has been followed in perhaps ten of the forty-five states, goes much further in controlling the business practices of the dealers. This type of statute commonly includes provisions for practical tests and written examinations, restrictions on advertising and pricing practices, requirements for continuing education, controls on the relationship between dealers and medical personnel, a statutory right of rescission, and injunctive powers for the enforcing authority. The third type of statute, adopted by three jurisdictions during the mid-1970's, omits the board approach to licensing and instead deals directly with what the legislature has felt to be the underlying cause of consumer complaints. Such a statute simply bars any individual from selling, dispensing or fitting any hearing aids without a written recommendation from a physician. This Article will compare the state statutes in an attempt to determine which have been the most effective in protecting individuals who are hard of hearing.<sup>8</sup>

#### COMPOSITION OF THE BOARD OF HEARING AID DEALERS

Of the forty-five states that have enacted legislation regulating the hearing aid industry, forty-two have created a board of hearing aid dealers.<sup>9</sup> The board is typically comprised of five<sup>10</sup> or seven<sup>11</sup> indi-

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9,286 (1977). See also Hearing Aid Industry Rules, 16 C.F.R. § 214 (1977); Medical Device Amendments Law of 1976, Pub. L. No. 94-295, which gives the FDA authority to require that medical devices be safe and effective before they reach the marketplace depending on the potential risk to the consumer. For a brief history of federal activity, see BERGER, *supra* note 2, at 133-34.

8. This Article will not deal with the problems of those individuals whose hearing is so impaired that they may be described as deaf. See generally L. MYERS, *THE LAW AND THE DEAF* (1964). This Article will not focus on the problems of noise in society. See generally NOISE POLLUTION AND THE LAW (J. Hildebrand, ed. 1970); Noise Control Act of 1972, 42 U.S.C. §§ 4901-4918 (1973).

9. Minnesota, New York and Vermont have not created a licensing board.

10. See, e.g., MISS. CODE ANN. § 73-14-9 (Supp. 1977); OHIO REV. CODE ANN. § 4747.03 (Page Supp. 1975).

11. See, e.g., HAW. REV. STAT. § 451A-3 (Supp. 1975); MICH. COMP. LAWS ANN. § 338.1454 (1976). However, the size of the state boards can vary from three members in Nevada, NEV. REV. STAT. § 637A.040 (1975), to nine members in Kentucky, KY. REV. STAT. § 334.140 (Supp. 1976).

viduals who are appointed by the governor with the advice and consent of the state senate.<sup>12</sup> Only in Tennessee<sup>13</sup> are all members of the board licensed hearing aid dealers. In the other jurisdictions, the statutes require a diversity of individuals on the board. The most common approach<sup>14</sup> is to require perhaps three or five dealers, one audiologist<sup>15</sup> and one otolaryngologist<sup>16</sup> on the Board. The statutes commonly give the voluntary professional organizations of hearing aid dealers within the state the power to make recommendations to the governor.<sup>17</sup> Some states require that the dealers appointed to the board be connected with a national hearing aid organization<sup>18</sup> or be actually certified by the National Hearing Aid Society.<sup>19</sup> In light of the apparent ease with which certification by the National Hearing Aid Society is granted,<sup>20</sup> it is questionable whether this membership is helpful or necessary. All three regulatory approaches permit out-

12. See, e.g., MD. ANN. CODE art. 43, § 750(2) (1971). *Contra*, ARIZ. REV. STAT. § 36-1902 (1971) (authorizing Director of the Department of Health Services to make the appointments).

13. TENN. CODE ANN. § 63-1501 (1976). The Louisiana Board consists of seven dealers and the State Health Officer. LA. REV. STAT. ANN. § 37:2455 (West 1974).

14. Missouri may typify the most common approach. See MO. REV. STAT. § 346.120 (Vernon Supp. 1976).

15. See, e.g., R.I. GEN. LAWS § 5-49-15 (1976). An audiologist is an "individual whose primary interest is in the identification and measurement of hearing loss and the rehabilitation of those with hearing impairments." NEWBY, AUDIOLOGY 1 (3d ed. 1972) [hereinafter cited as NEWBY]. The profession of audiology resulted from a combination, during World War II, of otology and speech pathology. Many audiologists have master's degrees in audiology or a related field and have been certified as clinically competent by the American Speech and Hearing Association. *Id.* at 376-92. See the definition of audiologist at VT. STAT. ANN. tit. 18, § 4581 (Supp. 1977). For an example of a state statute regulating audiologists, see ARK. STAT. ANN. § 72-1801 (Supp. 1975).

16. See, e.g., N.J. STAT. ANN. § 45:9A-3 (West Supp. 1977). An otolaryngologist is a physician who specializes in disorders of the ear, nose and throat. An otologist is a physician who specializes in disorders of the ear only. L. BOIES, J. HILGER & R. PRIEST, FUNDAMENTALS OF OTOLARYNGOLOGY 1 (4th ed. 1964) [hereinafter cited as BOIES]. There are approximately 2,000 audiologists and 7,000 otolaryngologists in the country. ELDERLY, *supra* note 4, at 307, 326.

17. See, e.g., CONN. GEN. STAT. ANN. § 20-397 (West Supp. 1976); GA. CODE ANN. § 84-5613 (1975); IOWA CODE ANN. § 154A.2 (West Supp. 1977). See also S.D. COMPILED LAWS ANN. § 36-24-3 (1972), which automatically makes the President of the Hearing Aid Dealers Association of South Dakota a member of the state board.

18. See, e.g., KAN. STAT. ANN. § 74-5802 (1972) (amended 1976).

19. See, e.g., N.J. STAT. ANN. § 45-9A-3 (West Supp. 1977); S.D. COMPILED LAWS ANN. § 36-24-3 (1972); TENN. CODE ANN. § 63-1501 (1976). The National Hearing Aid Society is a trade association of approximately 2200 hearing aid dealers who become "Certified Hearing Aid Audiologists" by taking a 20-lesson home study course and an examination. In addition to proposing a model licensing statute in the mid 1960's, it has been active in continuing education, ethical issues and consumer relations within the industry. INVESTIGATIONS, *supra* note 3, at 135-68. For a brief history of the NHAS, see BERGER, *supra* note 2, at 122-24.

20. STAFF STUDY, *supra* note 1, at 3-6. See *How to Buy a Hearing Aid*, CONSUMER REPORTS 346, 350 (June 1976).

side organizations to have some control, and occasionally significant control, over who is a member of the state licensing board.

In addition to political<sup>21</sup> and geographical<sup>22</sup> limitations on the composition of the board, the statutes frequently limit Board connections with hearing aid manufacturers. For example, Nevada forbids members of the board from holding stock in a corporation which manufactures hearing aids.<sup>23</sup> In order to insure that the board is free from competitive control, some states require that no more than two dealers be connected with the same hearing aid manufacturer.<sup>24</sup>

However, some states have structured their statutes so as to deal with a variety of problems and interests unique to the hearing aid industry. Several states specifically provide that the director of the state board of health or representatives of other state agencies be on the board.<sup>25</sup> In addition to the dispensers and the audiologists,<sup>26</sup> some state boards also are comprised of individuals who have no connection with the hearing aid industry. These independent members are placed on the board as representatives of the public.<sup>27</sup> For instance, Colorado provides that four members of the seven-member board be individuals who are not licensed by or employed in any health care occupation.<sup>28</sup> Since 1973, South Dakota has required one board member to be a lay person, and, if possible, a user of the services.<sup>29</sup> This requirement is based on the view that a user can provide the board with a more intimate knowledge of the needs of hearing aid consumers. Conversely, Rhode Island provides that the board shall include one lay member who is unconnected with hearing aids, audiologists, or state agencies.<sup>30</sup> The language of the statute

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21. See DEL. CODE, tit. 16, § 2014 (1975).

22. See, e.g., FLA. STAT. ANN. § 468.124 (West Supp. 1977); LA. REV. STAT. ANN. § 37:2455 (West 1974); TENN. CODE ANN. § 63-1501 (1976) (one member "from each grand division of the state").

23. NEV. REV. STAT. § 637A.050 (1975).

24. IND. CODE ANN. § 25-20-1-7 (Burns 1974); TEX. REV. CIV. STAT. ANN. art. 4566-1.02 (Vernon 1976).

25. KY. REV. STAT. § 334.140 (Supp. 1976); S.C. CODE § 40-25-40 (1977).

26. The antagonism between dealers and audiologists is revealed in *The Evolving Hearing Aid Dispensing System*, HEARING INSTRUMENTS 22 (December 1976) (interview with National Hearing Aid Society attorney). Compare ELDERLY, *supra* note 4, at 35-39. See also TENN. CODE ANN. § 63-1723 (1976), which creates a type of interlocking agency by requiring that a hearing aid dealer be included on the regulatory board of audiologists.

27. See, e.g., ARIZ. REV. STAT. § 36-1902(A)(1) (1974); CONN. GEN. STAT. ANN. § 20-397(b) (West Supp. 1977). A model bill proposed by an association of senior citizens urged the inclusion of more consumers on regulatory boards. ELDERLY, *supra* note 4, at 19.

28. COLO. REV. STAT. § 12-65-102(2) (Supp. 1976).

29. S.D. COMPILED LAWS ANN. § 36-24-4.1 (Supp. 1976).

30. R.I. GEN. LAWS § 5-49-15 (1976).

suggests that Rhode Island would exclude from membership on the board any hearing aid user, certainly a questionable policy. Maine provides that one member of the State Committee on Aging shall be on the board of hearing aid dealers.<sup>31</sup> Mississippi provides that one person shall be recommended by the Mississippi School for the Deaf.<sup>32</sup> Particularly in light of evidence that dealers have frequently dominated the boards,<sup>33</sup> the traditional makeup of the boards could be altered so that the hard of hearing have more impact on the operation and enforcement of the hearing aid statutes. This goal could be accomplished by placing more non-dealers on the board.

The members of the board usually are appointed for a four-year term.<sup>34</sup> Most statutes provide that members of the board are entitled to reimbursements for expenses, but otherwise serve without compensation.<sup>35</sup> A minority of boards do permit compensation, ranging from a fee of fifteen to twenty dollars a day with an annual total not exceeding five hundred to one thousand dollars.<sup>36</sup> Such compensation limits may make it difficult to obtain qualified persons for increasingly time-consuming positions.

### *Powers of the Hearing Aid Board*

Approximately sixty percent of the hearing aid boards are self-governing regulatory boards. The remainder are merely advisory boards to the state department of health or to some similar agency. However, the powers which are granted to either the hearing aid board or to the state board of health for enforcement of the hearing aid act are basically the same. The boards customarily are empowered to prepare and administer examinations, to issue licenses, to suspend and revoke licenses, to adopt regulations, to hire consultants and to take whatever administrative steps are necessary to carry out the act.<sup>37</sup>

Many states have granted more specific powers to the boards. As a common example, the Arkansas board is required to periodically in-

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31. ME. REV. STAT. tit. 32, § 1660-A (Supp. 1976).

32. MISS. CODE ANN. § 73-14-9 (Supp. 1977).

33. STAFF STUDY, *supra* note 1, at 6-8, 27-34.

34. *See, e.g.*, N.C. GEN. STAT. § 93D-3(a) (1975).

35. *See, e.g.*, N.M. STAT. ANN. § 67-36-3(F) (1974); N.D. CENT. CODE § 43-33-15(4) (Supp. 1977).

36. *See, e.g.*, OKLA. STAT. ANN. tit. 59, § 1551 (West Supp. 1976).

37. *See, e.g.*, DEL. CODE tit. 16, § 2015 (1975); MD. ANN. CODE art. 43, § 751 (1971). The Kentucky Attorney General has ruled that these general powers permitted the board to appoint a special investigative committee to discover violations of the statute. 73 OP. ATT'Y GEN. 619 (1973).

spect the facilities of hearing aid dealers and to test the audiometers used in testing hearing.<sup>38</sup> The Delaware hearing aid council is authorized to develop standardized educational procedures,<sup>39</sup> and the California board is authorized to set up an educational course for dealers on the fitting and selection of hearing aids.<sup>40</sup> The Georgia board is empowered to draft procedure and equipment requirements, but those requirements are obviously limited because they cannot be "in conflict with acceptable practices currently employed by the hearing aid industry."<sup>41</sup> The Georgia legislature apparently is content to allow the profession to influence the regulatory board's development of policies. The Michigan board is required to appoint an advisory council composed of two audiologists, one physician, and one optometrist.<sup>42</sup> The optometrist apparently is selected to provide information on hearing aids that are contained in eye glasses.

The state board of health generally administers the hearing aid regulations in jurisdictions where the board of hearing aid dealers is solely advisory and not independent.<sup>43</sup> However, the hearing aid act is enforced by the Director of Consumer Affairs in New Jersey,<sup>44</sup> by the Department of State in New York,<sup>45</sup> and by the Attorney General in North Dakota.<sup>46</sup> In the State of Washington, the licensing of hearing aid dealers for unknown reasons is administered by the Department of Motor Vehicles.<sup>47</sup> These state agencies generally have the same powers to implement the policies advocated by the advisory boards as do the independent hearing aid boards. It is doubtful that an independent hearing aid board will guarantee better implementation of the individual state's hearing aid law. A comprehensive state board administering the act could likely apply more experience, competence and diligence to the legislative grant of authority than a board which meets infrequently, often lacks financial compensation, may not be properly staffed, and may be subject to industry control

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38. ARK. STAT. ANN. § 72-1704(f) (Supp. 1975).

39. DEL. CODE tit. 16, § 2015(3) (1975). *See also* IOWA CODE ANN. § 1544A.4 (West Supp. 1977), which directs the board to develop exams based on those given by other states.

40. CAL. BUS. & PROF. CODE § 3327 (West 1974). *But see* OP. TEX. ATT'Y GEN. M-715 (November 2, 1970), which held that the Texas board did not have the implied authority to conduct educational seminars related to the hearing aid industry.

41. GA. CODE ANN. § 84-5614 (1975).

42. MICH. COMP. LAWS ANN. § 338.1455(g) (1976).

43. *See, e.g.*, FLA. STAT. ANN. § 468.123 (West Supp. 1977); W. VA. CODE § 16-24-4 (Supp. 1976).

44. N.J. STAT. ANN. § 45:9A-17 (West Supp. 1976).

45. N.Y. GEN. BUS. LAW § 786 (McKinney Supp. 1976).

46. N.D. CENT. CODE § 43-33-01 (Supp. 1977).

47. WASH. REV. CODE ANN. § 18.35.010 (Supp. 1977).



or institutional bias.<sup>48</sup> If the hearing aid board effectively advises its parent agency, then its recommendations should have at least as much impact on the actual enforcement of the act as if it were independently enforcing the act.

### *Financing the Regulation*

In fiscal 1975, the average state hearing aid board had an annual budget of \$12,500.<sup>49</sup> Funding for the boards, whether they were advisory or independent regulatory agencies, is derived primarily from fees that are paid by holders of the licenses. The initial fee for the examination and license for the first year ranges from five dollars<sup>50</sup> to one hundred dollars.<sup>51</sup> The annual renewal license typically costs seventy-five dollars per year.<sup>52</sup> Iowa simply provides that the annual fees shall be set by the board and shall be based upon the cost of operating the board and administering the act.<sup>53</sup>

Some statutes provide that the fees collected shall go to the general fund of the state and the board shall then be funded by legislative appropriations.<sup>54</sup> In a majority of states, however, the license fees go into a special fund to be used to pay the costs of operating the board of hearing aid dealers.<sup>55</sup> Some states have provided specifically that no general revenue funds of the state shall be applied to operate the hearing aid board.<sup>56</sup> The New Jersey statute goes so far as to say that the expenditures of the board shall not exceed the revenues during any fiscal year.<sup>57</sup> Such financial restrictions, leading to a shortage of funds, may limit substantially the board's ability to enforce or administer the act. It is not clear why an agency that must regulate an industry must be expected to generate sufficient funds

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48. For a discussion of the institutional bias that may exist in self regulation, see McCormack, *The Purpose of Due Process: Fair Hearing or Vehicle for Judicial Review?* 52 TEX. L. REV. 1257, 1262-72 (1974) [hereinafter cited as McCormack]. The bias that existed in the Kentucky regulatory scheme is revealed in STAFF STUDY, *supra* note 1, at 6-9, 27-34.

49. STAFF STUDY, *supra* note 1, at 61.

50. See, e.g., HAW. REV. STAT. § 451A-7 (Supp. 1975).

51. See, e.g., ME. REV. STAT. tit. 32, § 1658-H (Supp. 1976).

52. See, e.g., COLO. REV. STAT. § 12-65-111 (Supp. 1975). The renewal rate ranges from five dollars per year in Hawaii, HAW. REV. STAT. § 451A-8 (Supp. 1975), to one hundred twenty five dollars per year in Washington, WASH. REV. STAT. § 18.35.090 (Supp. 1975).

53. IOWA CODE ANN. § 154A.17 (West Supp. 1977).

54. See, e.g., ARIZ. REV. STAT. § 36-1903 (1974).

55. See, e.g., FLA. STAT. ANN. § 468.1281 (West Supp. 1977); NEB. REV. STAT. § 71-4718 (1976).

56. See, e.g., OKLA. STAT. ANN. tit. 59, § 1565 (West Supp. 1976); W. VA. CODE § 16-24-3 (Supp. 1976).

57. N.J. STAT. ANN. § 45:9A-18 (West Supp. 1976).

from that industry to pay the cost of operation. Although these restrictive statutes certainly could be changed, their inclusion in the general provisions suggests that the legislators did not consider the need for hearing aid regulation great enough to justify using funds from the general revenues.

#### THE LICENSING OF HEARING AID DEALERS

The statutes, after creating an administrative framework, define "hearing aid" and related terms for the purpose of restricting those who may engage in the practice. Those individuals who sell hearing aids are described alternatively as hearing aid dealers,<sup>58</sup> dispensers,<sup>59</sup> specialists,<sup>60</sup> fitters,<sup>61</sup> or practitioners.<sup>62</sup> A hearing aid usually is defined as "any wearable instrument or device designed for or offered for the purpose of aiding or compensating for impaired human hearing, and any parts, attachments or accessories, including ear molds, but excluding batteries and cords."<sup>63</sup> The statutes customarily include the ear mold as part of the aid, but exclude batteries and cords which are sold over-the-counter by retail establishments throughout the country.

The statutes then define the phrase "practice of fitting and dealing in hearing aids" as including, but not limited to, "the selection, adapting or sale of hearing aids or parts thereof; the testing of hearing by means of an audiometer or equivalent measurement of hearing; and the making of impressions for ear molds."<sup>64</sup> Some states have

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58. See, e.g., CONN. GEN. STAT. ANN. § 20-396 (West Supp. 1976).

59. See, e.g., ARIZ. REV. STAT. § 36-1901 (1974).

60. NEV. REV. STAT. § 637A.020 (1975).

61. See, e.g., OHIO REV. CODE ANN. § 4747.01 (Page 1977). See also OP. KY. ATT'Y GEN. 73-672 (September 25, 1973), which criticizes the imprecise language of that statute for indiscriminately referring to "fitters," "dealers and fitters," and "dealers or fitters."

62. DEL. CODE tit. 16, § 2001 (1975).

63. ME. REV. STAT. tit. 32, § 1658 (Supp. 1976). See also the broad definitions of OR. REV. STAT. § 694.015 (1975) ("any prosthetic instrument or device designed for or represented as aiding, improving or correcting defective human hearing and any parts, attachments or accessories of such an instrument or device") and VT. STAT. ANN. tit. 18, § 4581 (Supp. 1977). Compare the more technical and limiting definition of N.J. STAT. ANN. § 45:9A-2 (West Supp. 1977). For a more comprehensive discussion of the technology of hearing aids, see NEWBY, *supra* note 15, at § 321-334; BOIES, *supra* note 16, at § 160-166; HEARING AND DEAFNESS § 284-305 (H. DAVIS & S. SILVERMAN eds., 3rd ed. 1970) [hereinafter cited as DAVIS]; E. CORLISS, HEARING AIDS 4-7 (1970). See generally *Hearing Aids*, CONSUMER REPORTS 310-20 (May 1970).

64. See, e.g., ME. REV. STAT. tit. 32, § 1658 (Supp. 1976). One who takes an ear impression, has an impression made, and then sells that impression as a component part of a hearing aid is engaged in selling hearing aids and must be licensed. OP. TEX. ATT'Y GEN. M-895 (June 29, 1971).

defined the practice of fitting and dealing more broadly. For example, Arizona regulates those who make audiograms for a physician.<sup>65</sup> In Delaware, the statute includes those who use an otoscope or ear light to evaluate the feasibility of and use in ear molds and ear mold impressions.<sup>66</sup> Florida defines fitting or dealing in terms of advising or assisting in the purchase of aids or adjusting aids.<sup>67</sup> These latter provisions bring individuals under the hearing aid statutes who may not even be engaged in the sale of aids.

The statutes, in prohibiting a non-licensed individual from selling hearing aids, define "sale" as "any transfer of title or of the right to use [the aid] by lease, bailment, or any other contract."<sup>68</sup> However, the definition usually excludes wholesale transactions,<sup>69</sup> transactions between distributors or dealers,<sup>70</sup> and the "temporary, charitable loan or educational loan of a hearing aid without remuneration,"<sup>71</sup> thus limiting the statute basically to retail sales for profit.

### *Exclusions from Licensing*

After initially requiring licensing of those who are involved in the fitting and selling of hearing aids, the typical statutes proceed to exclude a number of individuals who fall under the state's definition of fitting and selling. All the states exclude individuals licensed under the appropriate medical statutes.<sup>72</sup> In addition, some statutes also exclude osteopaths<sup>73</sup> and audiologists.<sup>74</sup> While permitting the testing of hearing, most statutes prohibit a physician or audiologist from selling aids.<sup>75</sup> But some statutes are unclear as to whether the physician is permitted to sell a hearing aid without being licensed or whether the exclusion merely permits him to test hearing but without selling an aid.<sup>76</sup> The preferred reading of the statutes, as supported by most professionals,<sup>77</sup> suggests that the physician should be entirely

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65. ARIZ. REV. STAT. § 36-1901 (1974). *See also* HAW. REV. STAT. § 451A-1 (Supp. 1975).

66. DEL. CODE tit. 16, § 2001 (1975).

67. FLA. STAT. ANN. § 468.122(6)(a) (West Supp. 1977). *See* the unique and comprehensive definition of "hearing aid orientation" in ME. REV. STAT., tit. 32, § 1658(6) (Supp. 1976).

68. *See, e.g.*, IDAHO CODE § 54-2901 (Supp. 1977).

69. *See, e.g.*, ALA. CODE tit. 46, § 150(21)(G) (Supp. 1974).

70. *See, e.g.*, HAW. REV. STAT. § 451A-1 (Supp. 1975).

71. *See, e.g.*, IOWA CODE ANN. § 154A.1 (West Supp. 1977).

72. *See, e.g.*, MISS. CODE ANN. § 73-14-5 (Supp. 1977).

73. *See, e.g.*, N.D. CENT. CODE § 43-33-04 (Supp. 1975).

74. *See, e.g.*, N.M. STAT. ANN. § 67-36-7 (1974).

75. *See, e.g.*, R.I. GEN. LAWS § 5-49-4 (1976). *See also* OP. KY. ATT'Y GEN. § 73-826 (November 30, 1973).

76. *See, e.g.*, N.J. STAT. ANN. § 45:9A-22 (West Supp. 1977), which suggests that a physician may sell a hearing aid without being licensed.

77. *See* INVESTIGATIONS, *supra* note 3, at 4-18.

barred from selling an aid, because the profit motive may interfere with professional independence and judgment.

In addition, the statutes commonly exclude from licensing regulations an individual who works for a charitable institution or who is associated with an institution of higher education in a curriculum connected with hearing. Such individuals are commonly free to fit hearing aids provided that they do not sell them.<sup>78</sup> Another common exclusion is that a corporation may sell and fit hearing aids, provided that the corporation is properly registered and that the only individuals who actually fit and sell as employees of the corporation are also properly licensed.<sup>79</sup>

A number of states have specific provisions dealing with more unusual and sometimes questionable exclusions from the basic licensing requirements. For example, Arkansas specifically excluded chiropractors from the licensing requirements,<sup>80</sup> although the relevancy of that occupation to hearing problems is tenuous. Rhode Island<sup>81</sup> permits anyone to measure hearing, provided that they do not sell hearing aids. This type of statute allows volunteer organizations to do basic screen testing in the public schools. The California statute does not regulate catalog or direct mail sales, so long as no advice is given for fitting or selecting an aid or ear mold.<sup>82</sup> Oklahoma simply permits anyone to measure hearing and even to make and fit ear molds, provided that there is no sale of a hearing aid.<sup>83</sup> The exclusions of Arkansas and Oklahoma could reveal legislative surrender to vested interests, rather than a real concern for the hearing handicapped public, because of the substantial numbers of persons excluded from the regulatory provisions of the statutes.

### *License Requirements*

There are generally four requirements for a license to sell aids. The applicant for a license is typically required to be at least either 18 or 21 years old, to have the equivalent of a high school education, to be of good moral character, and to be free of contagious or infectious

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78. *See, e.g.*, ARIZ. REV. STAT. § 36-1921 (1974).

79. *See, e.g.*, COLO. REV. STAT. § 12-65-105 (Supp. 1976).

80. ARK. STAT. ANN. § 72-1706(6) (Supp. 1975).

81. R.I. GEN. LAWS § 5-49-4 (1976).

82. CAL. BUS. & PROF. CODE § 3351.5 (West 1974). *But see* text accompanying notes 234-235 *infra*.

83. OKLA. STAT. ANN. tit. 59, § 1557 (West Supp. 1976).

disease.<sup>84</sup> The age requirement in many states is now 18,<sup>85</sup> and the high school education requirement frequently is eliminated for those who have sufficient experience, at least sufficient experience before the particular statute was enacted.<sup>86</sup> In defining good moral character, Indiana denies a license to anyone previously involved in a crime of moral turpitude.<sup>87</sup> In contrast, a criminal record in Oklahoma is only evidence of a lack of good moral character.<sup>88</sup> Iowa unwisely permits consideration of a past felony record only if it directly relates to the fitting and licensing of hearing aids.<sup>89</sup>

Some states require applicants to be residents of the state.<sup>90</sup> Connecticut requires that the applicant be a United States citizen.<sup>91</sup> On the other hand, Iowa provides that one should not be ineligible because of citizenship, although information as to citizenship, age, sex, race, and marital status may be requested.<sup>92</sup> Several states require that no license be issued until the applicant is employed at an established place of business.<sup>93</sup> Florida requires that if a dealer does not have an established place of business at a permanent address open during normal business hours, then he must be employed by an individual meeting these requirements.<sup>94</sup> Such statutes make it difficult

84. See, e.g., N.C. GEN. STAT. § 93D-5 (1975); TEX. REV. CIV. STAT. ANN. art. 4566-1.06 (Vernon 1976). As to the application for a license in general, see COOPER, STATE ADMINISTRATIVE LAW 484-491 (1965) [hereinafter cited as COOPER]; MCCORMACK, *supra* note 48, at 1272-1278; *Gibson v. Berryhill*, 411 U.S. 564 (1973).

85. See, e.g., KY. REV. STAT. § 334.050(3) (Supp. 1976).

86. See, e.g., ARIZ. REV. STAT. § 36-1923 (1974). As to the validity of those educational requirements, compare STAFF STUDY, *supra* note 1, at 10 with *The Adequacy of Training for Hearing Aid Specialists*, AUDECIBEL 182 (Fall 1976).

87. IND. CODE ANN. § 25-20-1-3 (Burns 1974). However, the statute still must be enforced. The Senate committee heard of a California individual who honestly informed the board on his application that he had been convicted of several crimes, including assault and sodomy with a sheep, but who was still licensed by the board, despite the requirement of good moral character.

88. OKLA. STAT. ANN. tit. 59, § 1558 (West Supp. 1976).

89. IOWA CODE ANN. § 154A.9 (West Supp. 1977).

90. See, e.g., KAN. STAT. ANN. § 74-5811 (1972); S.D. COMPILED LAWS ANN. § 36-24-17 (1972). See also OP. KY. ATT'Y GEN. § 73-826 (November 30, 1973), which bars a non-resident from being licensed, or from receiving a training permit, even if sponsored by a licensed Kentucky hearing aid dealer. *Contra*, OP. TEX. ATT'Y GEN. M-636 (May 21, 1970), basis as a resident, whether by examination or under a grandfather clause.

91. CONN. GEN. STAT. ANN. § 20-400 (West Supp. 1976). But see *In re Griffiths*, 413 U.S. 717 (1973).

92. IOWA CODE ANN. § 154A.9 (West Supp. 1977).

93. See, e.g., ARK. STAT. ANN. § 72-1707 (Supp. 1975); W. VA. CODE § 16-24-5 (Supp. 1976) (applicant must intend to maintain a permanent office in the state or have a permanent office in another state within "reasonable commuting distance"). *Contra*, OP. TEXAS ATT'Y GEN. M-715 (November 2, 1970) (the Texas board may not require a business address within the state).

94. FLA. STAT. ANN. § 468.126(7) (West Supp. 1976).

for a licensed individual to start a new business. These restrictions of residency, citizenship and office never have been subjected to constitutional scrutiny, and it is questionable whether such statutory provisions could withstand an attack on constitutional grounds.

### *The Training Period*

After meeting the statutory prerequisites, the applicant generally must seek a temporary permit describing the holder as a trainee or apprentice. Temporary permits are customarily valid for one year or until thirty days after the next exam.<sup>95</sup> To obtain a license as a temporary trainee, the individual must show that he is being supervised by a current permit holder and that the current permit holder will give him training in the practice of fitting and dealing in hearing aids.<sup>96</sup> Although the applicant must list the name of the licensee who will be his supervisor, the statutes do not call for any specific training. Therefore, it is conceivable that a trainee could obtain a temporary license, wait until the next licensing exam and pass it without any practical training in the office of a hearing aid dealer.

Several states have drafted their statutes to prevent this weakness. North Carolina bars an individual from obtaining a permanent license until he has had an apprentice license for at least one year.<sup>97</sup> Thus, there is a minimum training period, although there is no requirement of any actual training during that period. Oklahoma law says in general terms that the supervisor shall maintain adequate contact with the trainee.<sup>98</sup> Maine requires that there be at least thirty days of actual supervision of the trainee.<sup>99</sup> North Dakota requires thirty hours of textbook study and ten hours of actual training on the audiometer before the trainee is allowed contact with the public. Then the trainee must spend one week in the office within a sixty day period, during which time he is not permitted to sell a hearing aid without the approval of the supervisor.<sup>100</sup>

Florida and Kentucky require the most elaborate and extensive training programs.<sup>101</sup> The training is divided into three stages,

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95. See, e.g., TENN. CODE § 63-1510 (1976).

96. See, e.g., ARIZ. REV. STAT. § 36-1926 (1974).

97. N.C. GEN. STAT. § 93D-5(c) (Supp. 1975).

98. OKLA. STAT. ANN. tit. 59, § 1561 (West Supp. 1976). See also WASH. REV. CODE ANN. § 18.35.060 (Supp. 1977). Washington permits a dealer to supervise only three trainees at a time.

99. ME. REV. STAT. tit. 32, § 1658-I(1) (Supp. 1976).

100. N.D. CENT. CODE § 43-33-08 (Supp. 1977).

101. FLA. STAT. ANN. § 468.126 (West Supp. 1977); KY. REV. STAT. § 334.090 (Supp. 1976). Both statutes permit a suitable university-level training course to substitute for stages one and two.

which must occur consecutively. During stage one, a period of thirty days, the trainee may not fit aids or test hearing, but may work in the office under the direct control of the licensee. During stage two, lasting sixty days, the trainee may test customers' hearing and make ear mold impressions. During stage three, which lasts for ninety days, a trainee may do everything that a licensed hearing aid dealer may do, but any work must be done under the supervision and control of a dealer. Only after completing this one hundred eighty days of training is the trainee qualified to take the exam and to receive his own license. These two states have the only training program adequately providing for both supervision and actual training.<sup>102</sup>

### *The Licensing Examination*

After meeting the requirements of the statute and the training requirements, forty-two states require the applicant to pass an exam before being licensed.<sup>103</sup> That exam is given on a frequency ranging from once a year<sup>104</sup> to once every three months.<sup>105</sup> Other states have more flexible standards. Nebraska says that an individual should be able to take an exam thirty days<sup>106</sup> after applying for a license, which results in a situation in which the Nebraska board may be giving the exam twelve times a year.

The statutes begin with a basic written exam, testing on subjects including: (1) the basic physics of sound;<sup>107</sup> (2) the anatomy and physiology of the ear;<sup>108</sup> and (3) the functions of the hearing aid.<sup>109</sup> In addition, nearly all the states call for practical tests of competency.<sup>110</sup> These commonly include questions on: (1) pure tone audiometry;<sup>111</sup> (2) air conduction testing;<sup>112</sup> (3) bone conduction test-

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102. Unfortunately, the Kentucky statute has not been applied fairly and completely. See STAFF STUDY, *supra* note 1, at 27-29. Pennsylvania recently has adopted a similar approach. PA. STAT. ANN. tit. 35, § 6700-306(b) (Purdon Supp. 1977).

103. From 1970 to 1974, 73% of those taking the exam nationwide passed. STAFF STUDY, *supra* note 1, at 60.

104. See, e.g., IOWA CODE ANN. § 154A.11 (West Supp. 1977).

105. See, e.g., IND. CODE ANN. § 25-20-1-11 (Burns 1974).

106. NEB. REV. STAT. § 71-4707 (1976).

107. See generally NEWBY, *supra* note 15, at 5-17.

108. See generally, BOIES, *supra* note 16, at 5-20; D. DEWEESE & W. SAUNDERS, TEXTBOOK ON OTOLARYNGOLOGY, 250-65 (3d ed. 1968) [hereinafter cited as DEWEESE].

109. See generally DAVIS, *supra* note 63, at 280-317.

110. See, e.g., ARK. STAT. ANN. § 72-1708 (Supp. 1975). But see GA. CODE ANN. § 84-5609 (1975).

111. Pure tone audiometry utilizes an instrument to generate electronically tones of essential "purity," similar to those produced by a tuning fork. The audiometer then measures the threshold level of hearing at various frequencies. Hearing loss is measured, in decibels, as the

ing;<sup>113</sup> (4) masking;<sup>114</sup> (5) recording and evaluation of audiograms;<sup>115</sup> and (6) the taking of ear mold impressions.<sup>116</sup> The statutes usually provide that the test shall not require any college training or medical competency.<sup>117</sup> Some states actually provide that there shall be no testing of audiological skills.<sup>118</sup>

A number of the states test on subjects other than medical and practical areas. Arizona tests the applicant's knowledge of the hearing aid code of ethics;<sup>119</sup> West Virginia tests on the dealer's knowledge of the grounds for revocation and suspension of a license.<sup>120</sup> Several statutes require that the applicant be tested on his knowledge of the medical rehabilitation facilities for hard of hearing individuals.<sup>121</sup> Arkansas tests the live voice or recorded voice speech audiometry, including speech reception, threshold testing, and speech discrimina-

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difference between the threshold level, when the impaired ear can just barely detect the presence of the tone and zero decibels, the theoretical point at which the average normal ear can detect the presence of the test tones 50% of the time. NEWBY, *supra* note 15, at 67-70. See also DEWEESE, *supra* note 108, at 282-84.

112. Normally we hear by air conduction. Most sounds are air borne; the sound waves are directed by the outer ear down the ear canal to the ear drum, relayed across the ossicular bones of the middle ear to the fluid systems of the inner ear, and then transmitted via the VIIIth nerve to the brain. Air conduction testing determines the ability to hear in this fashion. NEWBY, *supra* note 15, at 25-30, 73-81.

113. Hearing also occurs by bone conduction. Since the inner ear is encased in bone, vibration of this bone will cause the fluid of the inner ear to move, even if those vibrations have not proceeded through the ear canal, the ear drum and the middle ear. However, hearing by bone conduction is less efficient than by air conduction. To set the bones of the skull in movement, vibrations must be more intense. In addition, in traveling through the head, rather than through the canal, some sounds are not accurately transmitted. *Id.* at 30-31. Perhaps only 1% of hard of hearing individuals are able to use bone conduction more satisfactorily than air conduction. DAVIS, *supra* note 63, at 323. If the air conduction tests disclose no hearing loss, then the hearing examination is effectively ended. But if the air conduction test does disclose a hearing loss, then the bone conduction test is given to determine if the loss is due to conduction or sensori-neural factors. The bone conduction test is performed by placing a small vibrator on the temporal bone behind the outer ear. NEWBY, *supra* note 15, at 82-90.

114. Masking occurs in any hearing situation when noise of any kind interferes with the audibility of another sound. Because of the potential difference in hearing capabilities of an individual's two ears, it may be advisable to introduce a masking tone into one ear while testing the hearing of the other ear. *Id.* at 17, 79-80.

115. The audiogram is a graph containing the results of the hearing examination, charted according to intensity and frequency of the tones. *Id.* at 100-09.

116. For a discussion of the techniques of marking ear mold impressions, see BERGER, *supra* note 2, at 98-107. For examples of potential malpractice liability resulting from the making of ear mold impression, see *Palmer v. Miller*, 60 F. Supp. 710 (W.D. Mo. 1945); *Persten v. Chesney*, 212 S.W.2d 469 (Mo. App. 1948).

117. See, e.g., N.D. CENT. CODE § 43-33-07 (Supp. 1977).

118. See, e.g., KY. REV. STAT. § 334.060 (Supp. 1976).

119. ARIZ. REV. STAT. § 36-1924 (1974).

120. W. VA. CODE § 16-24-6(3) (Supp. 1976).

121. See, e.g., DEL. CODE tit. 16, § 2007 (1975); MD. ANN. CODE art. 43, § 743(c) (1971).



tion testing.<sup>122</sup> Maine tests the applicant's knowledge of cros and bi-cros fittings, knowledge of master hearing aid or sound pressure measurement, and knowledge of relevant consumer laws.<sup>123</sup>

The Oklahoma statute provides that the written exam shall follow the guidelines of the exams of the National Hearing Aid Society.<sup>124</sup> Michigan has the only statute which provides that the written exam given by the state board may be waived if the applicant has completed the home study course of the National Hearing Aid Society.<sup>125</sup> Particularly in light of the criticism of the simplicity of that course,<sup>126</sup> such a waiver is not appropriate, for the State of Michigan is delegating its regulatory powers to a private self-interest group which may not have the same goals as the state.

### *Reciprocal and Grandfather Licenses*

Most states allow licenses to be obtained through processes other than the general examination procedure. First, some states provide that a certificate or license of endorsement can be obtained based upon a current valid license that has been issued by another state. Those individuals who are licensed elsewhere may qualify for a certificate of endorsement if the issuing board concludes that the standards in the first state are substantially equal to its own standards.<sup>127</sup> The applicant then is entitled to practice his profession without taking the exam. Some states require not only the same requirements in each state, but also a clear policy of reciprocity between the two

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122. ARK. STAT. ANN. § 72-1708(b)(2)(b) (Supp. 1975). Speech audiometry, similar to pure tone audiometry, determines the patient's threshold hearing level. But rather than hearing a tone, the patient hears a list of two syllable words. Speech audiometry is also used to determine the level at which speech is most comfortable, the level at which it is uncomfortably loud and the ability to discriminate among sounds. NEWBY, *supra* note 15, at 120-34. See also DAVIS, *supra* note 63, at 206-18.

123. ME. REV. STAT. tit. 32, § 1658-K(2) (Supp. 1976). Florida even attempts to test the ability of the dealer to counsel the individual who will receive and use the hearing aid. FLA. STAT. ANN. § 468.127(3) (West 1977). See also W. VA. CODE § 16-24-6(3) (Supp. 1976). There is a need for counseling because even when an aid is properly fitted, most new users of an aid go through a period of adjustment as they begin hearing, with mechanical assistance, those sounds that they have not heard for some time. In addition, various adjustments may have to be made so that the user can receive optimum benefit from the aid. See *How to Buy a Hearing Aid*, CONSUMER REPORTS 346, 349 (June 1976); E. CORLISS, HEARING AIDS 5-8 (1970); DAVIS, *supra* note 63, at 312-16, 318-31.

124. OKLA. STAT. ANN. tit. 59, § 1562 (West Supp. 1976).

125. MICH. COMP. LAWS ANN. § 338.1456(5) (1976).

126. STAFF STUDY, *supra* note 1, at 3-6. But see INVESTIGATIONS, *supra* note 3, at 212-14.

127. See, e.g., MICH. COMP. LAWS ANN. § 338.1456 (1976); S.C. CODE § 40-25-100(2) (1977).

states.<sup>128</sup> Under the Kentucky statute, a valid license from another state does not exempt one from the Kentucky examination, but merely permits one to omit the training period of one hundred eighty days in Kentucky.<sup>129</sup>

The statutes do not always clarify the relationship between the certificate of endorsement and the requirement in some states of residency. The need for a certificate of endorsement applies not only to the individuals who may move from one state to another, but also to those who live near a state border and who may work in two states while being a resident of only one. For example, the Florida certificate of endorsement apparently is limited to individuals who actually move to Florida, not to individuals who may reside in another state and wish to sell in Florida on an occasional basis.<sup>130</sup>

Second, approximately half of the states originally had a grandfather clause providing that an individual with generally two or three years<sup>131</sup> experience at the time the statute was enacted would be licensed without taking the exam.<sup>132</sup> As of 1975, almost half the licensed dealers had been admitted under such provisions.<sup>133</sup> Frequently these practitioners were admitted with minimal experience or qualifications to serve the public in this fashion.<sup>134</sup> Other statutes did not award licenses automatically. For example, the Mississippi law merely gave a dealer with two years' experience at the time the statute was enacted two years to pass the exam, whereas one without that experience would have to pass the exam immediately.<sup>135</sup> However questionable such provisions were, their impact will decline progressively as new dealers are licensed and as continuing education is required.

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128. See, e.g., GA. CODE ANN. § 84-5608 (1975). See also OP. TEX. ATT'Y GEN. M-1063 (1973), which permits a dealer to receive a Texas license by endorsement regardless of whether the original license was obtained by examination, grandfather clause or reciprocity with a third state.

129. KY. REV. STAT. § 334.080(2) (Supp. 1976).

130. FLA. STAT. ANN. § 468.126(6) (West 1977). See also N.M. STAT. ANN. § 67-36-8(c) (1974).

131. See, e.g., W. VA. CODE § 16-24-7(6) (Supp. 1976) (three years); S.C. CODE § 56-745.5 (Supp. 1975) (two years).

132. Individuals who had been performing administrative or executive functions in hearing aid companies may have been "dealing" in aids, but may not have been "fitting" aids and therefore could not be licensed under the grandfather provisions. 73 OP. KY. ATT'Y GEN. 672 (1973).

133. STAFF STUDY, *supra* note 1, at 6.

134. See STAFF STUDY, *supra* note 1, at 27-31. One permissible means of checking the qualifications of a grandfather applicant was to require a list of ten customers to be furnished with the application. 73 OP. KY. ATT'Y GEN. 623 (September 5, 1973).

135. MISS. CODE ANN. § 73-14-29 (Supp. 1977). See also NEB. REV. STAT. § 71-4706(2) (1976).

REGULATIONS ON THE PRACTICE OF FITTING  
AND DEALING IN HEARING AIDS

*Continuing Education*

After the applicant is licensed as a hearing aid dealer or fitter, he generally may engage in the business for a one year period. The applicant is then free from any future examinations or educational requirements, except in those seven states which require continuing education. North Dakota provides that before a license can be renewed there must be two days a year of continuing education, but the statute does not place any requirements on the nature of that continuing education.<sup>136</sup> The New Jersey and North Carolina hearing aid committees are authorized to consider a requirement of continuing education,<sup>137</sup> while the Michigan statute requires in general terms that an applicant shall furnish "satisfactory evidence that he has studied current educational materials in the hearing aid field during the previous year."<sup>138</sup>

Colorado, Iowa and Kansas have the most stringent laws. These statutes provide that before an individual may have his license renewed, he must complete one of the following programs: a continuing education program conducted by the board; a session conducted by the National Hearing Aid Society which has been approved by the board; or a session conducted by a hearing aid manufacturer which has also been approved by the board.<sup>139</sup> In light of the frequent developments in the hearing aid, medical and audiological professions, it seems only appropriate that all states adopt either by statute or regulation the requirement of continuing education. Even admitting that the benefit gained from some sessions may be minimal and that the cost of training would be passed on to the consumer, such a requirement should be viewed as an honest attempt to upgrade the training of those individuals who are to protect and help the public.<sup>140</sup>

*Sales Receipts*

Virtually all the statutes require that a specific receipt be given to individuals who purchase hearing aids. Typically, the statute requires

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136. N.D. CENT. CODE § 43-33-11 (Supp. 1977).

137. N.J. STAT. ANN. § 45:9A-8 (West Supp. 1977); N.C. GEN. STAT. § 930-3(c)(12) (Supp. 1977).

138. MICH. COMP. LAWS ANN. § 338.1457(2) (1976).

139. COLO. REV. STAT. § 12-65-112 (Supp. 1976); IOWA CODE ANN. § 154A.16 (West Supp. 1977); KAN. STAT. ANN. § 74-5821 (1972).

140. The National Hearing Aid Society now requires 10 hours of continuing education annually for members to retain their status. See Florida Hearing Aid Society Newsletter 2,6 (March 1977).

that anyone buying a hearing aid receive a receipt that describes the name, address and license number of the dealer, the nature of the aid and its condition, the guarantee provisions, and specific price information.<sup>141</sup> In addition, most statutes require that the receipt contain specific language, in large type, that the buyer has been advised that the seller gave no medical opinion or medical diagnosis.<sup>142</sup> A number of states require the receipt to state that when the seller initially contacted the buyer, he was advised that no medical opinion would be given.<sup>143</sup> Because of the danger that many potential users may believe that a hearing aid dealer is a medical expert, the inclusion of such warning language is appropriate.

The receipts are required to list the total price of the aid and any down payment. North Carolina additionally requires the cost of the hearing aids and the fees for testing and fitting services to be listed separately.<sup>144</sup> Such a breakdown of the costs may discourage buyers from seeking post-purchase adjustments, fitting or counselling if they are charged separately for those services. On the other hand, those individuals who do not need those particular services will not have to pay for them, and others may seek them from a different source.<sup>145</sup> South Dakota, which like North Carolina requires specifically that the buyer sign the receipt, also says that the signature shall constitute his full "acknowledgement."<sup>146</sup> It is unclear what importance the South Dakota legislature attaches to a receipt which was signed by the consumer.

The most elaborate receipt provisions are found in Maine and Kentucky. Maine requires that a receipt which is delivered prior to or at sale include, in addition to the general information, the address of the

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141. See, e.g., ARIZ. REV. STAT. § 36-1932 (1974).

142. See, e.g., COLO. REV. STAT. § 12-65-117(2) (Supp. 1976); TEX. REV. CIV. STAT. ANN. art. § 4566-1.14(c) (Vernon 1976).

143. See, e.g., R.I. GEN. LAWS § 5-49-3(b) (1976); WIS. STAT. ANN. § 459.03(6) (West 1974). For instance, the suggested purchase agreement prepared by the Kentucky board has the following language in large type at the top of the contract:

The purchaser has been advised at the outset of his relationship with the hearing aid dealer that any examination or representation is not an examination, diagnosis or prescription by a person licensed to practice medicine in this state and therefore must not be regarded as medical opinion or advice.

See also N.Y. GEN. BUS. LAW § 784(9) (McKinney Supp. 1976) which requires the written statement that "[t]his aid will not restore normal hearing nor will it prevent further hearing loss."

144. N.C. GEN. STAT. § 93D-7 (Supp. 1975).

145. See ELDERLY, *supra* note 4, at 22-26, 66-68. The Federal Trade Commission has proposed a partial "unbundling" of the costs involved in the purchase of a hearing aid. 40 Fed. Reg. 26645 (1975).

146. S.D. COMPILED LAWS ANN. § 36-24-33 (1977).

board of hearing aid dealers, the trade-in allowance, and the statutory provision that the audiologist or a medical doctor may permit cancellation of the sale if the dealer has provided an aid that is not advisable.<sup>147</sup> The Kentucky law requires a conspicuous statement on the receipt that any complaints may be referred to the hearing aid board, that the buyer has a thirty day right to cancel the contract for the purchase, and that there has been no home visit without prior written consent.<sup>148</sup> Such comprehensive provisions are a necessary means of protection.

### *Sales to Minors*

Because of greater health, educational and cultural risks, twenty-eight states have a specific statutory provision regulating the sale of hearing aids to children. The definition of child generally includes persons under sixteen years of age.<sup>149</sup> The statutes commonly provide that an aid shall not be sold to a child unless that child has been examined by a physician within ninety days prior to the fitting of the aid.<sup>150</sup> If the child has not seen a physician within that ninety day period, the statutes require that the dealer or dispenser shall recommend in writing that a physical examination take place. The inherent weakness in such a statute is that the child or his parents are still free to ignore the recommendation and purchase the aid without ever seeing a physician.

In order to overcome this avoidance of the recommendation, some statutes bar the dealer from selling an aid unless a physician's hearing test within ninety days has determined that there are no physical deficiencies that would prohibit the effective use of a hearing aid.<sup>151</sup> Although this is an improvement over the recommendation provision, this type of statute only requires the doctor to state that a hearing aid would not be effective, without concluding that a hearing aid may provide some benefit to the user. Some states further require that the

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147. ME. REV. STAT. tit. 32, § 1658-C (Supp. 1976).

148. KY. REV. STAT. § 334.030 (Supp. 1976). The Kentucky law also requires that the seller disclose orally the condition of any used hearing aid prior to any signing of a receipt or contract.

149. See, e.g., COLO. REV. STAT. § 12-65-117(3) (Supp. 1976); OHIO REV. CODE ANN. § 4747.09 (Page 1977). However, the statutes vary in their definition of the age under which a person is considered a child. For example, the Alabama statute defines children as persons under the age of ten, ALA. CODE tit. 46, § 150(23) (Supp. 1973), while the Washington statute refers to children as being under age eighteen, WASH. REV. CODE ANN. § 13.35.110(2)(e)(ii) (Supp. 1975).

150. See, e.g., OKLA. STAT. ANN. tit. 59, § 1556C (West Supp. 1976); W. VA CODE § 16-24-14(a) (Supp. 1976).

151. See, e.g., N.D. CENT. CODE § 43-33-12(8) (Supp. 1976); WIS. STAT. ANN. § 459.035 (West 1974).

child also be "cleared for a hearing aid" by that physician.<sup>152</sup> The most stringent statutes bar the sale to a child unless that child has been examined and has received a recommendation for an aid from a physician.<sup>153</sup> Finally, a handful of states prohibit a dealer from selling to anyone, regardless of age, until there has been a specific medical recommendation for a hearing aid.<sup>154</sup>

The statutes commonly provide that the examination must be conducted by a physician. However, a number of states require that the examination be given by an ear-nose-throat specialist.<sup>155</sup> Mississippi suggests that the exam be given by either a medical physician or an audiologist,<sup>156</sup> in the process failing to distinguish the functions of both professions.<sup>157</sup> On the other hand, Connecticut requires that the child be examined and cleared for an aid by both an ear-nose-throat specialist and an audiologist.<sup>158</sup> It is deemed unethical in Washington to sell to a minor unless that individual has been examined and cleared by an ear-nose-throat specialist in the past six months who has not advised that the child go to a clinical audiologist for an examination.<sup>159</sup> The statutes do make exceptions to the requirement for an examination of a child if the dealer is merely replacing an identical aid fitted within the past two years,<sup>160</sup> if the parents have "good cause,"<sup>161</sup> or if the parents file a written objection on religious grounds.<sup>162</sup>

Acting under authority granted by the Food, Drug and Cosmetic Act<sup>163</sup> and the Medical Device Amendments of 1976,<sup>164</sup> the Commissioner of the Food and Drug Administration has recently promulgated federal regulations that significantly affect key aspects of the hearing

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152. See, e.g., MISS. CODE ANN. § 73-14(3)(g)(9) (Supp. 1977).

153. See, e.g., CAL. BUS. & PROF. CODE § 3365.6 (West 1974); IOWA CODE ANN. § 154A.20 (West Supp. 1977); ME. REV. STAT. tit. 32, 1658-D (Supp. 1976).

154. See text accompanying notes 206-214 *infra*.

155. See, e.g., CAL. BUS. & PROF. CODE § 3365.6 (West 1974); IOWA CODE ANN. § 154A.20 (West Supp. 1977).

156. MISS. CODE ANN. § 73-14-3(g)(9) (Supp. 1977).

157. The apparent antagonism between medical specialists and audiologists is revealed in a series of articles in AUDECIBEL, the journal of the National Hearing Aid Society, *Financially Motivated Clinical Audiologists Open Attack on Otolaryngologists*, Winter 1976, page 9; Spring 1976, page 74; Summer 1976, page 136. See also "ACO Sub-Committee on Hearing Aids Issues Report," AUDECIBEL, Winter 1977, at 9.

158. CONN. GEN. STAT. ANN. § 20-404(a)(6) (West Supp. 1977); See also DEL. CODE tit. 16, § 2001(8)(m) (1975); N.M. STAT. ANN. § 67-36-1(F) (1974).

159. WASH. REV. CODE ANN. § 18.35.110(2)(e)(ii) (Supp. 1977).

160. See, e.g., N.J. STAT. ANN. § 45:9A-25 (West Supp. 1977).

161. See, e.g., OR. REV. STAT. § 694.136(7) (1975).

162. See, e.g., COLO. REV. STAT. § 12-65-117(4) (Supp. 1976).

163. 21 U.S.C. §§ 301-392 (1970).

164. Pub. L. No. 94-295.

aid industry.<sup>165</sup> Effective August 25, 1977, the FDA now requires that before a person under age eighteen may be sold an aid, the minor must first be examined by a licensed physician.<sup>166</sup> Unlike some state statutes, the federal requirement cannot be waived for any reason. However, the FDA requirement does not require that the physician actually recommend a hearing aid. The physician must only state that the patient may be "considered as a candidate for a hearing aid." Another potentially troublesome provision states that the examination must have taken place only within the past six months, rather than the past thirty or ninety days. Finally, the FDA does not require an examination by an otolaryngologist or a clinical audiologist, even though both specialists generally are recommended. In a specific notice to be given to all prospective hearing aid users, they are advised that "a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child."<sup>167</sup>

It is uncertain how the new FDA regulations affect the state laws. As originally proposed, the regulation would have permitted the states to enact "more stringent requirements."<sup>168</sup> But the final regulation omits that provision. The Medical Device Amendments of 1976 provide for automatic federal pre-emption of inconsistent state laws. However, state authorities still may petition the Commissioner to exempt a state requirement if it is more stringent, or if it is necessitated by "competing local conditions."<sup>169</sup> Therefore, states are free to petition the FDA to permit a state requirement, for example, that a minor be examined by an otolaryngologist or an audiologist or that a physician specifically recommend a hearing aid. Such petitions may be necessary if minors with hearing problems are to be fully protected.

165. The regulations, both procedurally and substantively, were approved subsequently in *American Speech and Hearing Ass'n v. Califano*, CCH Med. Devices Rep. ¶¶ 15,004; 15,007 (D.D.C. December 19, 1977). See also *Levin v. Kennedy*, CCH Med. Devices Rep. ¶ 15,006 (S.D. Fla. October 25, 1977) (equal protection challenge rejected).

166. 42 Fed. Reg. 9285, 9296 (1977)(to be codified in 21 C.F.R. 801.420(a)(2)).

167. *Id.* at 9295 (21 C.F.R. 801.420(c)(3)).

168. 41 Fed. Reg. 16755, 16763 (1976).

169. Section 521(b) of the Medical Devices Amendments of 1976, Pub. L. No. 94-295. The FDA has rejected one petition that raised the pre-emption issue. *Med. Devices Rep. (CCH) ¶¶ 13,851; 17,161*. Challenges to state statutes on the ground that the federal regulations pre-empted the area have been dismissed because the regulations had not been finally adopted. See *New Jersey Guild of Hearing Aid Dispensers v. Long*, 145 N.J. Sup. 580, 368 A.2d 929 (Super. Ct., App. Div. 1976); *New York State Hearing Aid Society Inc. v. State of New York*, *Med. Devices Rep. (CCH) ¶ 15,001* (E.D.N.Y., December 3, 1976).

*Medical Referral*

The statutes of sixteen states require that if a hearing aid dealer discovers specific medical conditions during the course of his examination, that dealer must refer the customer to a medical physician. Medical conditions described by the statutes<sup>170</sup> include: (1) visible congenital or traumatic deformity of the ear;<sup>171</sup> (2) a history of active drainage from the ear in the past ninety days; (3) a history of rapidly progressing hearing loss in the past ninety days;<sup>172</sup> (4) acute or chronic dizziness; (5) unilateral hearing loss of recent onset in the past ninety days; (6) significant air bone gap;<sup>173</sup> and (7) visible evidence of cerumen accumulation or a foreign body in the ear canal.<sup>174</sup> These

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170. See, e.g., CAL. BUS & PROF. CODE § 3365.5 (West 1974); COLO. REV. STAT. § 12-65-118 (Supp. 1976). In 1975, the National Hearing Aid Society adopted, as part of its Code of Ethics, the "Guidelines of Medical Clearance." If the dealer, during the course of the examination, detects one of the seven conditions, the dealer "must urge the client to seek medical help. If the client refuses, the fact should be noted on the waiver and signed by the client. In fact, it is advised that if any of one of the seven criteria is observed, the client should not be fitted with a hearing instrument." National Hearing Aid Society, Guidelines for Medical Clearance (1976). INVESTIGATIONS, *supra* note 4, at 201-04.

171. For a discussion of the medical significance of these conditions, see generally BOIES, *supra* note 16, at 86-154; DEWEESE, *supra* note 108, at 299-339.

172. Hearing losses generally can be classified in two categories. Conductive losses are those that can be traced to the outer or middle ear. The hearing difficulty results from the manner in which sound is conducted to the analyzing system, not with the perception of sound as such. A conductive loss, which may be caused by ear canal blockage, middle ear infection or otosclerosis, a progressive softening and weakening of the ear bones, may be corrected by antibiotics or, in some cases, by surgery. NEWBY, *supra* note 16, at 34-46. The vast majority of hearing losses, perhaps as much as 95%, falls into the second category, that of sensori-neural hearing losses. If the loss results from the pathology in the inner ear or in the nerves connecting the inner ear with the brain, it may have been caused by heredity, a prenatal illness, childhood disease, long exposure to loud noises, or the aging process. Unlike conductive impairments, a sensori-neural loss generally cannot be helped through treatment or surgery. Once the nerves transmitting the sounds have been destroyed, they cannot be recreated or regenerated. *Id.* at 46-56. See also DEWEESE, *supra* note 108, at 340-61; DAVIS, *supra* note 63, at 88-136. Hearing aids are most effective for persons with a conductive loss, for the hearing aid is simply required to amplify the sound. On the other hand, a sensori-neural loss, often includes difficulty with particular sounds or frequencies. A hearing aid, while potentially of assistance to many individuals, is not as effective with this second type of loss. Most of the recent technological developments have been toward producing aids that do permit a response for different frequencies. See DEWEESE, *supra* note 108, at 275-76, 278; DAVIS, *supra* note 63, at 100-01; BOIES, *supra* note 16, at 164; INVESTIGATIONS, *supra* note 3, at 219-20.

173. The air-bone gap is the difference in decibels between the hearing threshold levels as determined by air conduction and bone conduction tests. *Id.* at 500. See also the specific definition of OR. REV. STAT. § 694.136(6)(f) (1975). Compare ARIZ. REV. STAT. § 63-1901(7)(t) (1975) and FLA. STAT. ANN. § 468.135(5) (West Supp. 1977) (medical referral limited to this sixth condition).

174. An accumulation of cerumen, or wax, in the ear canal may prevent sound from reaching the ossicular bones of the middle ear. The removal of the excess by a physician may improve hearing substantially without need for any mechanical assistance. NEWBY, *supra* note 15, at 20, 36. See also DEWEESE, *supra* note 108, at 303-04.



conditions suggest that the hearing difficulties may be corrected by medicine or surgery and in such instances an aid may be unnecessary. The medical conditions actually may be aggravated in some instances by the presence of an artificial object in the ear and such conditions may be indicators of substantial medical problems unconnected with hearing difficulties.<sup>175</sup>

Some of the sixteen states merely provide that if the medical condition exists, the dealer has a responsibility to recommend to the customer that it is in his best interest to see a physician before seeking a hearing aid.<sup>176</sup> However, the customer is still free to ignore that advice and to purchase a hearing aid without seeking a medical opinion. The state of Washington says that a customer must be notified in writing of the need to see an ear-nose-throat specialist and that the dealer shall not discourage the buyer from going to such a specialist.<sup>177</sup> New Jersey provides further that after the dealer has told the prospective buyer to see a physician, preferably an otologist, the buyer must sign a receipt saying that he has received such advice, and the dealer must provide the buyer with the names of three doctors qualified to examine him.<sup>178</sup> Maine<sup>179</sup> and Minnesota<sup>180</sup> have the toughest requirements, providing that if the medical conditions have been detected, the dealer shall delay fitting a hearing aid until he has consulted a physician or an audiologist. While these two statutes do make referral mandatory, their significance is diminished by permitting examination by an audiologist, who lacks extensive medical training.

The new regulations of the FDA also seek to promulgate referral guidelines. The new regulations state that if the hearing aid dispenser discovers any one of eight otologic conditions, he should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid.<sup>181</sup> However, this regulation is weaker than both the originally proposed requirement and some state requirements. As originally proposed, the requirement stated that a seller "shall not allow a pros-

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175. For a discussion of the possible medical and surgical procedures, see generally BOIES, *supra* note 16, at 74-85; DAVIS, *supra* note 63, at 164-75; DEWEESE, *supra* note 108, at 348-60.

176. See, e.g., OKLA. STAT. ANN. tit. 59, § 1556(D) (West Supp. 1976); W. VA. CODE § 16-24-14(b) (Supp. 1976).

177. WASH. REV. CODE ANN. § 18.35.110(2)(e)(i) (Supp. 1977).

178. N.J. STAT. ANN. § 45:9A-24 (West Supp. 1977).

179. ME. REV. STAT. tit. 32, § 1658-D(2) (Supp. 1976).

180. MINN. STAT. ANN. § 145.55(1) (West Supp. 1976).

181. The eighth condition is pain or discomfort in the ear. 42 Fed. Reg. 9285, 9295 (1977) (to be codified at 21 C.F.R. 801.420(c)(2)). But see INVESTIGATIONS, *supra* note 3, at 79-80 (hearing aid dealers are unqualified even to detect these eight conditions).

pective user to waive the medical evaluation requirement" if any of the conditions were revealed.<sup>182</sup> The FDA ultimately changed the specific conditions of the medical evaluation from "shall not allow" a waiver to "should advise" consultation with a doctor.<sup>183</sup>

In its concern with those few individuals who may object to seeing a physician on medical, financial or personal freedom grounds, the FDA may be providing insufficient protection to those suffering from one of the eight conditions who elect to ignore the dealer's "advice" to consult a doctor before buying an aid. Although the FDA-mandated language informs the user that "the exercise of such a waiver is not in your best interest and its use is strongly discouraged," and the FDA further expects that hearing aid dispensers will be "conscientious in impressing the importance of a medical examination upon prospective users exhibiting any of these symptoms,"<sup>184</sup> it would have been more beneficial to the public interest to require referral to a physician in these instances, thus limiting the opportunity for a waiver in light of the medical risks present.

### *Door-to-Door Sales*

Door-to-door canvassing in order to sell hearing aids particularly has been attacked for taking advantage of homebound and elderly individuals who are unable to shop for reasonably priced aids and who may be more susceptible to sales presentations. Therefore, six hearing aid statutes place specific restrictions on door-to-door selling. Delaware simply has incorporated by reference its basic home solicitation statute.<sup>185</sup> The Rhode Island statute, like most general solicitation statutes, gives the hearing aid buyer a right to cancel the purchase within three days if the sale was consummated at a place other than at the seller's business address.<sup>186</sup>

The other four states are more restrictive. New York bars any door-to-door canvassing for the purpose of selling or renting hearing aids without the prior request of the customer.<sup>187</sup> Similarly, Michigan bars canvassing house-to-house without a prior request or referral,<sup>188</sup> but the language of the statute suggests that a third party,

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182. 41 Fed. Reg. 16755, 16763 (1976).

183. 42 Fed. Reg. 9285, 9288, 9291 (1977).

184. *Id.* at 9291, 9295.

185. DEL. CODE tit. 16, § 2020 (1975).

186. R.I. GEN. LAWS § 5-49-3(C) (1976).

187. N.Y. GEN. BUS. LAW § 784(2) (McKinney Supp. 1976). A similar New Jersey regulation was upheld in *New Jersey Guild of Hearing Aid Dispensers v. Long*, 145 N.J. Sup. 580, 368 A.2d 929 (Super. Ct., App. Div. 1976).

188. MICH. COMP. LAWS ANN. § 338.1461(j) (1976).

even if interested, could refer a dealer to a prospective customer. The Kentucky statute requires written consent prior to a visit. The consent must indicate that the customer is aware that the dealer may attempt to sell a hearing aid during that visit.<sup>189</sup> Hawaii takes the simplest approach and bans any door-to-door solicitation for the purpose of selling aids.<sup>190</sup> Unfortunately, these statutes do not clarify whether the customer's response to dealers' and manufacturers' advertising may suffice as effective consent.

The Federal Trade Commission previously has dealt with door-to-door sales by requiring on an individual basis that advertisements designed to produce "leads" include a warning that a salesman might call on those individuals who responded to the advertisements.<sup>191</sup> However, the FTC recently has proposed a significantly broader provision similar to that of Kentucky. If the regulation is adopted, no seller will be able to visit the home of a potential buyer for the purpose of inducing a sale unless the customer previously has given express written consent to the visit.<sup>192</sup> Therefore, the consent would have to state clearly and conspicuously that the potential buyer is aware that the seller may attempt to sell a hearing aid during the visit. The proposed regulation does not clarify whether an effective consent could be contained in the advertising forms that are to be returned to the dealer or manufacturer.

It is questionable whether such regulations are helpful. Even the most naive buyer is unlikely to believe that individuals go door-to-door discussing hearing aids without a profit motive. Yet perhaps such a restriction does help to distinguish more clearly the profit-oriented hearing aid dealer from clinics or institutes that provide hearing services.

### *Right of Rescission*

In contrast with vision losses, hearing losses are more difficult to diagnose and to correct.<sup>193</sup> In addition, a hearing aid will be worn in a variety of listening situations, ranging from private conversations to public meetings. The hearing aid that may appear effective and beneficial in the dealer's office may turn out not to provide assistance in the environment in which the user actually lives and works. There-

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189. KY. REV. STAT. § 334.030(2) (Supp. 1976).

190. HAW. REV. STAT. § 451A-14(b) (Supp. 1975).

191. 40 Fed. Reg. 26645, 26651 (1975).

192. *Id.* at 26648.

193. E. CORLISS, HEARING AIDS 5-6 (1970). See also NEWBY, *supra* note 15, at 329-34; DAVIS, *supra* note 63, at 322, 327; ELDERLY, *supra* note 4, at 57, 204.

fore, the idea of a trial period before the purchase of a hearing aid has been advocated.<sup>194</sup>

Seven state statutes have provided the hearing aid purchaser with a variation on a money-back guarantee.<sup>195</sup> North Carolina simply gives the board the duty to establish regulations guaranteeing a full refund to the buyer when an ear-nose-throat specialist provides a written opinion that the buyer's hearing cannot be improved by an aid.<sup>196</sup> However, this statutory language may make it difficult for the buyer to obtain a written opinion from an ear-nose-throat specialist, particularly when the physician may have limited knowledge of the capabilities of hearing aids and when the buyer may have limited access to the specialist.

The state of Washington similarly provides that the buyer has a right to rescind within thirty days of purchase, based upon a medical opinion recommending against the use of an aid.<sup>197</sup> A time limit is included, a written opinion is not required, and the medical opinion need not specifically state that a hearing aid cannot improve the buyer's hearing. The Oregon statute provides that the buyer may rescind within forty-five days by giving a written notice to rescind.<sup>198</sup> Rescission may occur in Oregon if a medical doctor advises in writing against a hearing aid, if the seller has committed any unethical acts, or if the seller failed to provide a written statement prior to consummation of the sale as required by the statute. The written statement must include the basic receipt information, the address of the health department and the procedure for making a complaint, and general advice to consult a doctor. In case of rescission, the Oregon dealer is entitled to retain ten percent of the purchase price as reasonable rental for the thirty day period as well as the cost of the ear molds.

The remaining four statutes do not condition the right to rescind upon a medical opinion. Vermont simply provides that any sales contract shall include a thirty-day money-back guarantee. If the aid is not satisfactory, the purchaser may return the hearing aid in new condition and shall be entitled to receive the full product price, less the

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194. INVESTIGATIONS, *supra* note 3, at 71-74. The National Hearing Aid Society recently has required its members to adopt a rental/purchase option plan for all hearing aids to ensure a trial period. *Id.* at 203-04.

195. For cases discussing the buyer's right to rescind on other theories, see *Hagedorn v. Taggart*, 114 A.2d 430 (D.C. 1955); *Hagedorn v. Leroy*, 104 A.2d 606 (D.C. 1954); *Buchanan v. Dugan*, 82 A.2d 911 (D.C. 1951).

196. N.C. GEN. STAT. § 93D-3(c)(11) (1975).

197. WASH. REV. CODE ANN. § 18.35.190(3) (Supp. 1977).

198. OR. REV. STAT. § 694.042 (1975).

cost of ear molds and any service provided.<sup>199</sup> If the aid is returned undamaged, the dealer may sell it as a new aid to a second purchaser if its previous use is disclosed. The New York law, which also provides a thirty-day money-back guarantee, permits the dealer to retain the lesser of ten percent of the purchase price or thirty dollars, in addition to the specific cost for ear molds.<sup>200</sup> That cancellation charge also is adjusted annually for inflation according to the consumer price index. The returned aid may be resold as new only if it is reconditioned by the manufacturer, meets all the acoustical standards, and is warranted as a new hearing aid. Like the other rescission statutes, the New York provision supplements other remedies. Specifically, the purchaser retains rights to recover the full amount paid and any damages sustained for a breach of warranty of fitness for use.

Kentucky applies several significant variations to the money-back guarantee. The buyer's right to cancel for any reason must be explained in large type on the purchase receipt. The cancellation charge consists of fifteen dollars, the charge for any customer ear molds or batteries, and five percent of the remainder of the purchase price. The right to cancel does not apply to a hearing aid sold pursuant to a specific written recommendation by a physician or audiologist.<sup>201</sup>

Maine provides for the most unique cancellation provisions. The statute provides that at the time of the sale the seller may receive only fifty percent of the purchase price. From twenty to thirty-five days later, the seller is to make personal contact with the buyer and provide all necessary services such as repairs or an additional fitting of the aid. The buyer must be notified of his right to cancel. If during this period the buyer expresses his satisfaction with the hearing aid in writing, the balance of the purchase price is then due. However, during this trial period, the buyer may cancel the transaction for any reason by notifying the seller in writing. If the buyer does cancel the purchase, the dealer is entitled to ten percent of the purchase price plus the cost of the ear molds.<sup>202</sup>

The Federal Trade Commission proposal on hearing aids builds upon the four statutes which do not premise rescission on a medical

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199. VT. STAT. ANN. tit. 18, § 4583(b) (Supp. 1977).

200. N.Y. GEN. BUS. LAW § 784(4) (McKinney Supp. 1976).

201. KY. REV. STAT. tit. 32, § 334.210 (Supp. 1976). The Kentucky statute provides for a thirty-day money-back guarantee.

202. ME. REV. STAT. tit. 32, § 1658-B (Supp. 1976). In addition to the trial period cancellation, Maine also permits cancellation of the sale for medical reasons. *Id.* § 1658-C(4)(D).

opinion. Under the proposals, the buyer would be notified at the time of the purchase of his right to cancel the sale within thirty days.<sup>203</sup> Cancellation would occur by returning a cancellation notice to the buyer, without the need to state a medical or other reason for cancellation. If the sale is cancelled and the aid returned in relatively the same condition, the dealer would be required to return any old aid used as a trade-in, cancel any financial obligations incurred by the buyer and return any payments made. However, the seller would retain cancellation charges consisting of the cost of batteries and ear molds, and a thirty day rental fee, equal under one option to ten percent of the purchase price with a maximum of thirty dollars adjusted annually for inflation.

The proposed regulation should be refined before it is promulgated. While the thirty-day period is a reasonable time in which to test a hearing aid in a variety of situations, the cancellation charge should be simplified. A rental fee of ten percent of the purchase price, with perhaps eight percent on the amount of the purchase price over five hundred dollars, should sufficiently compensate the dealer for testing, fitting and counseling the user. Such a fee would neither penalize the buyer nor encourage him to cancel the sale whimsically.

The proposed regulation is not yet explicit in explaining what the dealer may do with an aid that is returned. If the FTC follows the New York approach, the hearing aid could be reconditioned by the manufacturer and then sold as new. However, the money from a cancellation fee may be insufficient to permit the dealer to recondition the aid and also to compensate him fairly for his time and services. In addition, the regulation as proposed requires the hearing aid dealer to return an aid taken as a trade-in. In effect, the dealer must hold that trade-in in his inventory for thirty days to see if the buyer exercises his right to cancel. The regulation should be amended to permit the dealer to refund the value of the used aid instead of the actual aid in order to allow the dealer to do as he wishes with the used aid.

Under the proposed FTC rule, which is similar to the Kentucky statute, the buyer would not have a right to cancel if the dealer merely sells an aid that has been recommended specifically by a physician or audiologist. Such a regulation is based on the assumption that a hearing aid dealer may make a mistake in selecting an aid but a physician or audiologist will not. But that assumption has flaws. Those two professionals may know less about hearing aids than a dealer, and

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203. 40 Fed. Reg. 26645, 26647-48 (1975).

regardless of the profession, the fitting of hearing aids is not an exact science. The right to cancel should apply to the sale of all aids, and the regulation should pass the financial risk of cancellation to the person prescribing or selecting the aid, regardless of whether he is an audiologist, physician, or dealer.

These attempts at a money-back guarantee<sup>204</sup> are indeed unique and not likely to be found in statutory schemes regulating other occupations or professions. However, they can be justified not only on the basis that persons buying hearing aids are more likely to be taken advantage of and need special protection, but more importantly because hearing aids are a unique product the value of which to a particular individual may not be predictable, and therefore a reasonable trial period outside the confines of the dealer's office is necessary.

### *Mandatory Medical Recommendation*

Perhaps seventy-five percent of all hearing aid purchasers never see a physician before purchasing an aid.<sup>205</sup> To reduce the possibility of dealers selling unnecessary or even harmful hearing aids, six states require that before a hearing aid can be sold, the medical physician must provide a written statement of authorization or recommendation.<sup>206</sup> Of these six states, three have traditional licensing statutes, one has a limited and simplified licensing statute, and the other two do not license dealers at all. Hawaii simply bars the dealer from selling a hearing aid without first obtaining a physician's written authorization based upon a medical examination within the last ninety days which has resulted in the doctor's prescription or approval of a

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204. Even in states that do not require the right of rescission by statute many dealers are voluntarily offering such rights to purchasers. One Florida dealer includes in all sales:

*30 Day Money Back Guarantee.* If the buyer is not completely satisfied, the buyer may return the hearing aid, with all accessories, to \_\_\_\_\_'s Hearing Aid Center within 30 days after the hearing aid was delivered and fitted (that is, by \_\_\_\_\_) and the buyer's money will be refunded, except for the cost of ear molds and the cost of dispensing fee (\_\_\_\_\_), which includes the case history, audiometric test and evaluation. This guarantee does not apply if during the 30 day period any damage to the hearing aid has resulted from accidental causes or negligence; Specifically, corroded battery contacts, scratched or cracked cases, damage of components resulting from exposure to excessive heat, immersion in liquid of any kind, dropping on a hard surface or any other damage not caused primarily by defective parts.

205. ELDERLY, *supra* note 4, at 6-7, 348-49.

206. In 1975 the National Hearing Aid Society adopted a variation of the mandatory medical recommendation. INVESTIGATIONS, *supra* note 3, at 201-04. In addition to weaknesses in the guidelines, the policy is binding only on NHAS members and is limited by the enforcement powers of a voluntary association. Maryland has recently adopted such a provision in 1977 MD. LAWS ch. 735, 769.

hearing device.<sup>207</sup> If the buyer is under the age of ten, the examination must be administered by an otolaryngologist. This requirement may not apply to a subsequent purchase of another hearing aid. Similarly, Pennsylvania bars the sale of a hearing aid unless a physician has made a written recommendation within the past six months that the use of an aid "may be beneficial" to the customer.<sup>208</sup>

Kentucky, which has a traditional licensing statute similar to Hawaii's, requires two written statements within the preceding ninety days.<sup>209</sup> A licensed physician must first approve of a hearing aid by concluding that the patient has no ear diseases or other conditions that might make the fitting and wearing of a hearing aid useless or harmful. Next, a physician or audiologist must make a hearing evaluation and recommend a hearing aid. That recommendation may include the make and model of a particular hearing aid or the appropriate hearing aid specifications. However, the strong consumer protection offered by the Kentucky and Pennsylvania statutes is undermined by permitting anyone over the age of eighteen to waive both written statements.

New York, which has a modified licensing statute, provides that a hearing aid shall not be sold unless within the previous six months there has been a simple written recommendation for a hearing aid from an ENT specialist or audiologist.<sup>210</sup> New York does not allow a waiver. The only opportunities for waiver are religious objections to a hearing aid examination or lack of an ENT specialist or audiologist in the community. In this situation, a medical physician in general practice may give a simplified hearing test and make his recommendations. Although the examination and recommendation procedure of New York is not as elaborate as that of Kentucky,<sup>211</sup> it does go further in barring any connection between the physician and dealer. Not only is the physician prevented from selling hearing aids for profit in New York, but the physician also cannot refer, suggest or

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207. HAW. REV. STAT. § 451A-14 (Supp. 1975).

208. PA. STAT. ANN. tit. 35, § 6700-403 (Purdon Supp. 1977).

209. KY. REV. STAT. § 334.100 (Supp. 1976). Kentucky also prohibits the physician from having any financial interest in the dealer's business. Thus, Kentucky prohibits an ear-nose-throat specialist from hiring a licensed hearing aid dealer as an employee or locating that hearing aid dealer in an adjoining office.

210. N.Y. GEN. BUS. LAW § 784(1) (McKinney Supp. 1976). Primarily because of its requirement of a written recommendation by an otolaryngologist or a licensed clinical audiologist, the New York statute was described as "impossible" by the dealers' association at the time of its enactment. National Hearing Aid Society, Confidential Report (October 1975).

211. However, the New York law, N.Y. GEN. BUS. LAW § 781(g) (McKinney Supp. 1976), permits a recommendation for a specific hearing aid.



recommend a patient to a specific dealer.<sup>212</sup> On the other hand, the physician may recommend or direct the patient to a professional association or to a directory of dealers.

Vermont and Minnesota have enacted statutes which do not license hearing aid dealers or fitters. Rather than promulgating an administrative licensing structure, Vermont simply bars anyone from selling a hearing aid unless the potential customer has obtained a written statement from a medical doctor based on an examination performed in the preceding six months.<sup>213</sup> The language of the Vermont statute, however, is so broad that a dealer could sell a hearing aid even if the doctor were indifferent to or actually opposed to the use of a hearing aid. The ear examination is not required if the buyer objects on religious grounds. However, the Vermont statute does state that no physician or audiologist may sell hearing aids either directly or indirectly for profit.

The Minnesota statute simply says that no one may sell a hearing aid without the written recommendation or prescription of either an audiologist or physician.<sup>214</sup> The Minnesota statute does not state clearly how specific the prescription must be. It is uncertain whether the doctor must say only that a hearing aid would be of benefit to the user or whether he must recommend specifically a particular hearing aid model. If the doctor determines the particular performance levels, then the hearing aid dealer becomes little more than a dispenser of an item selected by someone else. The function of a hearing aid dealer then would be limited to instructing the buyer in the use and maintenance of the aid.

The Minnesota statute does not indicate when the recommendation must be made by the doctor. The law permits anyone under the age of sixty to waive these rights and purchase the aid without a recommendation.<sup>215</sup> In order to waive the rights, the individual must receive a copy of the law in large print, and the law must be read aloud to him. Like the Kentucky provision, this waiver is a broad exception weakening the statute to the extent that it may not grant the protection intended.

In the most far-reaching aspect of the new federal regulations, the FDA has followed the lead of the six states which require medical

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212. *Id.* at § 785-a(1), (2).

213. VT. STAT. ANN. tit. 18, § 4582 (Supp. 1977).

214. MINN. STAT. ANN. § 145.32(2) (West Supp. 1976). The Minnesota statute was adopted following an investigation of the hearing aid industry in Minnesota by a consumer group. See its report, and the industry's response, in ELDERLY, *supra* note 4, at 243-51, 270-85.

215. MINN. STAT. ANN. § 145.44(2) (West Supp. 1976).

authorization. The regulations provide that a dealer shall not sell a hearing aid unless a physician has stated in writing that the patient's hearing loss has been evaluated medically within the past six months and that the patient "may be considered a candidate for a hearing aid."<sup>216</sup> The regulation does not require an examination by an ear specialist, as such physicians may not always be available in rural areas. The regulation further waives an examination by an audiologist because that type of testing would increase the cost of the aid and would not provide assurance that the aid actually would benefit the customer.<sup>217</sup> Thus, the FDA regulation in effect repeals the weakness of the New York and Minnesota approach in equating the physician and the audiologist.

As the federal regulations originally were proposed, the physician would have been required to assert that there were no medical reasons why the individual should not be fitted with a hearing aid.<sup>218</sup> However, because of a concern that the doctor might be unwilling to sign such a statement,<sup>219</sup> the language subsequently was altered so that the physician merely was required to state that his patient is a candidate for a hearing aid. Under the current regulations, the doctor need not conclude that the candidate can be helped by an aid, neither is he called upon to recommend or prescribe an aid.<sup>220</sup> The rationale behind the provisions is that the hearing aid dispenser, not the physician, should have knowledge of the performance level of aids and select the aid most likely to provide assistance. The FDA regulations permit the prospective user to waive the medical evaluation. But before permitting the customer to sign a waiver, the dispenser must inform the customer that the waiver is not in the customer's best health interest, review the contents of a User Instructional Brochure, give the customer an opportunity to read the brochure, and not actively encourage him to waive the medical evaluation.<sup>221</sup> The customer is free to waive the requirement of a mandatory medical evaluation for any reason.

The FDA regulations combine the best elements of the six state statutes. While permitting the doctor to refer the customer to an audiologist, the relevant regulation does not equate an audiologist with

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216. 42 Fed. Reg. 9285, 9296 (1976) (to be codified at 21 C.F.R. 801.421(a)(1)). See also 1977 MD. LAWS ch. 735, 769.

217. *Id.* at 9288-89. The opposition of the audiologists to the regulation is also discussed in *Special Report, AUDECIBEL*, 57 (Spring 1977).

218. 41 Fed. Reg. 16755, 16763 (1976).

219. 42 Fed. Reg. 9285-92 (1976).

220. *Id.* at 9288.

221. *Id.* at 9296 (21 C.F.R. 801.421(a)(2), (b)).

a physician by permitting the former to make a medical evaluation. While prescribing that the doctor must examine and consider the patient, it does not expect the doctor to be an expert in the mechanics of hearing aids or in the subjective art of fitting a hearing aid and counseling the user. While requiring a prerequisite medical evaluation for all, it does permit the user to waive the evaluation. This provision, combined with the medical referral in light of designated otologic conditions, effectively balances the need to identify that small percentage of users who may be helped by medicine or surgery, while not unnecessarily increasing the cost or inconvenience to the large majority who do not require medical treatment.

### *Miscellaneous Protections*

A number of state statutes have other unique provisions designed to protect purchasers and users of hearing aids. Several states have provided that the audiometers used by dealers for testing shall be calibrated periodically.<sup>222</sup> For example, Florida provides that the Department of Health shall set forth specific standards for testing equipment, accessories and office facilities.<sup>223</sup> Michigan requires that a complete retail price list of all hearing aid models be available for prospective clients.<sup>224</sup> Vermont provides that the complete terms of the sale must be disclosed in writing before the sale is consummated.<sup>225</sup>

A most significant consumer protection is now provided by the User Instructional Booklet which is required by the FDA regulation. The regulations would require that a booklet accompany each hearing aid given to a prospective user. Further, this booklet would be orally reviewed with each user before that individual waives the medical

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222. See, e.g., MO. REV. STAT. § 346.095 (Vernon Supp. 1976); WIS. STAT. ANN. § 459.085 (West 1974). By regulation, Arkansas has defined minimum requirements for an audiometer in terms of frequencies, intensity, air conduction receivers and bone conductor oscillators, and masking capabilities. Arkansas Board of Hearing Aid Dispensers, Rules and Regulations Article XVI, Section 1 (1973). The suggestion has been made that audiometers be calibrated periodically by the board, rather than relying on the dealer to have a third party make necessary adjustments. STAFF STUDY, *supra* note 1, at 9.

223. FLA. STAT. ANN. § 468.135 (West Supp. 1976). Since the results of a hearing test depend in large part on the conditions under which it was given, see NEWBY, *supra* note 15, at 73, and the person who gives it, the Florida Department of Health and Rehabilitative Services has recently adopted a regulation requiring all hearing tests to be given in a testing room certified by the Department not to exceed specified sound pressure levels at specified frequencies. See Reg. 10D-48. § 28(2), effective January 1, 1977. However, the significance of this requirement is undermined by the broad opportunity for a waiver given to the dealer and the client.

224. MICH. ADMIN. CODE, § 338.1922, Rule 22(1) (Supp. 1970).

225. VT. STAT. ANN. tit. 18, § 4583(a) (Supp. 1977).

evaluation,<sup>226</sup> a requirement that goes far beyond any state requirements. The thirteen specific types of information that would be given include specific instructions on the use and maintenance of the hearing aid, a description of known medical side effects to the use of a hearing aid, the statement that the aid will not restore normal hearing and must be used more than infrequently, the warning of the eight otologic conditions, the requirement of a medical evaluation and various technical data.<sup>227</sup> To ensure that all information is made available fairly and effectively to the user, the FDA has required that the User Instructional Booklet be approved prior to its distribution.<sup>228</sup> Even conceding that many users will not read the booklet and that some dispensers may not be as thorough as the FDA envisions in explaining the provisions, this requirement at least would provide the hard of hearing with the warnings and information that they have not always received.

#### ENFORCEMENT OF THE STATUTES

##### *Unethical Acts*

The acts prohibited by the statutes generally are described as either unlawful or unethical. The unlawful provisions relate closely to those adopted in other licensed occupations. The unlawful acts by a dealer include selling or bartering a license, purchasing or procuring a license by barter, altering a license, attempting to use an altered license, and making a false statement on the original application or renewal for a license.<sup>229</sup>

The state statutes focus more significantly on the unethical acts. These statutes customarily include a list of acts<sup>230</sup> that would be banned in any regulated industry. Such conduct includes habitual intemperance, gross immorality, permitting another individual to use a license, obtaining a fee by fraud, and employing an unregistered person. Several states have enacted more specific provisions to deal with

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226. 42 Fed. Reg. 9285, 9296 (1977) (to be codified at 21 C.F.R. 801.421 (b),(c)).

227. *Id.* at 9295. (21 C.F.R. 801.420(c)(1)).

228. *Id.* (21 C.F.R. 801.420(d)).

229. *See, e.g.,* ARIZ. REV. STAT. § 36-1936 (1974). Some states have supplemented this basic list of unlawful acts. For example, Texas law provides that it is unlawful for a dealer to fail to clearly disclose his name, business address and purpose in any telephone solicitation or to use or purchase any customer list compiled by other parties. TEX. REV. CIV. STAT. ANN. art. 4566-1.15(c) (1976).

230. *See, e.g.,* ARIZ. REV. STAT. § 36-1901(7) (1974). The South Dakota Board has the duty to establish ethical standards beyond those listed in the statute. S.D. COMPILED LAWS ANN. § 36-24-12 (Supp. 1976).

the hearing aid industry. For instance, a majority of states consider it unethical to sell a hearing aid to a child unless that child has been examined by an ENT specialist and cleared for a hearing aid within six months of the examination.<sup>231</sup> Indiana, on the other hand, states in its statute that it is unethical to sell a hearing aid to a person under the age of sixteen or over the age of seventy unless an adult with normal hearing is present when the sale is completed.<sup>232</sup> This approach, while uniquely providing some protection for the senior citizen, fails to provide any medical protection for the child.

In addition to those states which have attempted to regulate improper solicitation through door-to-door sales,<sup>233</sup> Idaho, for example, prohibits the dispensing of hearing aids by mail in any form.<sup>234</sup> Missouri takes a more limited approach by deeming it unethical to sell hearing aids through the mail unless there has been a prior fitting and testing by a licensed dealer.<sup>235</sup> Therefore, Missouri would permit a consumer to be tested and fitted in a hearing aid dealer's office and then receive the hearing aid by mail without the dealer personally delivering and fitting the aid. In light of the problems that may arise in adjusting the aid and counseling the user, such an approach ultimately may be impractical.

The legislatures have attempted to provide for a minimum quality of treatment and service by the dealer in defining unethical acts. A number of states simply declare it unethical to demonstrate gross incompetence or negligence in fitting or selling an aid.<sup>236</sup> For example, Colorado deems it an unethical practice to sell a hearing aid to an individual without testing him, except where the sale involves a replacement aid purchased within one year of the original purchase.<sup>237</sup> California includes improper or unnecessary fitting of a hearing aid in its definition of gross incompetence.<sup>238</sup>

There has long been a concern that hearing aid dealers have increased their sales by suggesting that they possess some degree of medical competency. Therefore, the statutes commonly view it as un-

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231. See text accompanying notes 160-175 *supra*.

232. IND. CODE ANN. § 25-20-1-22(7) (Burns 1974); See also LA. REV. STAT. ANN. § 37:2442(5)(v) (West 1974); MISS. CODE ANN. § 73-14(3)(g) (Supp. 1977).

233. See text accompanying notes 185-190 *supra*.

234. IDAHO CODE § 54-2913(f) (Supp. 1977). The FDA considered banning all mail order sales, but concluded that such a prohibition was not necessary. Mail order sales must, however, satisfy the requirements of the FDA regulation. 42 Fed. Reg. 9285, 9293 (1977).

235. MO. ANN. STAT. § 346.110(1) (Vernon Supp. 1976).

236. See, e.g., COLO. REV. STAT. § 12-65-114(g) (Supp. 1976); KY. REV. STAT. § 334.120(2)(g) (Supp. 1976).

237. COLO. REV. STAT. § 12-65-114(f) (Supp. 1976).

238. CAL. BUS. & PROF. CODE § 3401(a) (West 1974).

ethical for the dealer to make any medical analysis or prediction about the effect of a hearing aid on a hearing impairment.<sup>239</sup> Louisiana forbids the dealer from suggesting that his competency is based on a college education,<sup>240</sup> which would thus distinguish a hearing aid dealer from an audiologist. Oklahoma, along with other states, deems it unethical to use the term "clinical audiologist" improperly.<sup>241</sup> On the other hand, Mississippi permits the dealer to note that he is a "Certified Hearing Aid Audiologist" if the dealer has been so certified by the National Hearing Aid Society.<sup>242</sup>

The problem of advertising hearing aids has troubled legislatures. Following closely the regulations adopted by the Federal Trade Commission in 1965,<sup>243</sup> the states have passed general provisions for controlling advertising and more specific provisions in regard to unethical acts in the hearing industry. The states generally<sup>244</sup> have adopted provisions deeming it unethical to use misleading or deceptive advertising,<sup>245</sup> to use bait and switch tactics in advertising,<sup>246</sup> or to use a false name in advertising. The Kentucky law declares it unethical to advertise professional methods or professional superior-

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239. DEL. CODE, tit. 16, § 2001(8)(h) (1975).

240. LA. REV. STAT. ANN. § 37:2442(5)(S) (West 1974).

241. OKLA. STAT. ANN. tit. 59, § 1566(B)(3)(f) (West Supp. 1976).

242. MISS. CODE ANN. § 73-14-3(g)(3) (Supp. 1977). It is very doubtful that the public is aware of the distinction between an audiologist and a "Certified Hearing Aid Audiologist." See note 13 *supra*. The dispute over the phrase "Certified Hearing Aid Audiologist" has occurred at several levels. While some legislatures and the Attorney General of Idaho have permitted its use, the Attorney Generals of Georgia and Kentucky have ruled that its use by a dealer is improper. Compare AUDECIBEL 50 (Spring 1977) with OP. GA. ATT'Y GEN. (January 15, 1975) and 75 OP. KY. ATT'Y GEN. 454 (July 3, 1975). The American Speech and Hearing Association, the organization of clinical audiologists, has petitioned the United States Patent Office to cancel the registration of the trademark "Certified Hearing Aid Audiologist." National Hearing Aid Society, Confidential Report (October 1975). See also ELDERLY, *supra* note 4, at 108-09.

243. 16 C.F.R. § 214 (1977). The proposed FTC regulation would in part supersede these 1965 regulations and would closely parallel the advertising regulations discussed in these two paragraphs. 40 Fed. Reg. 26645 (1975). Two states have incorporated the FTC rules. NEB. REV. STAT. § 71-4712(2)(c)(xii) (1971); TEX. STAT. ANN. § 4566-110(10) (1976).

244. See, e.g., COLO. REV. STAT. § 12-65-114(c)(3), (c)(4), (e) (Supp. 1976); N.J. STAT. ANN. § 45:9A-17(c)(3), (c)(4), (c)(10) (West Supp. 1977).

245. See also 16 C.F.R. § 214.1, .14, .15 (1977). The Texas Attorney General refused to determine as a matter of law whether the use of a city name with the words "Hearing Aid Center," such as "Austin Hearing Aid Center," was deceptive or misleading advertising, and said it depended on the facts of a particular case and referred it to the Board. OP. TEX. ATT'Y GEN. H-375 (Aug. 21, 1974). Cf. 16 C.F.R. § 214.11 (1977).

246. See also the specific criteria of FLA. STAT. ANN. § 468.130 (West, 1977); 16 C.F.R. § 214.3 (1977). For an illustration and switch techniques, see Hagedorn v. Taggart, 114 A.2d 430 (D.C. 1955).

ity.<sup>247</sup> A California statute has prohibited the advertising of prices for hearing aids.<sup>248</sup>

In Florida, it is considered unethical for a dealer to suggest falsely that a hearing aid is a new invention,<sup>249</sup> that a hearing aid consists of "nothing in the ear," or that a hearing aid is custom made.<sup>250</sup> It is unethical in Louisiana to advertise that a hearing aid will restore or preserve hearing or retard future hearing loss.<sup>251</sup> Kentucky perhaps goes the furthest by forbidding the sale of any hearing aid that does not have the approval of the board of hearing aid distributors as to reasonable merchantability and workmanship.<sup>252</sup> It is not clear from the statute on what basis the Kentucky board would make such a determination, but perhaps the board could rely on the tests performed by the Veterans Administration.<sup>253</sup>

The unethical conduct provisions also deal with relationships between competitors. For example, in Arizona it is considered unethical to defame competitors, display competitive products in a way that disparages the products, falsely represent that competitors are unreliable, quote incorrect prices of competitive models, imitate or simulate trademarks in such a way as to deceive, use trademarks so as to substitute one product for another, or use competitive information through bribery or falsity.<sup>254</sup>

To insure that there are no kickbacks or payoffs in the hearing aid industry, the statutes customarily include provisions which deem it unethical to offer money to induce one to obtain purchasers.<sup>255</sup> Thus, it usually will be considered unethical for the hearing aid dealer to have a financial relationship with audiologists or physicians. It is considered unethical in Arizona to share profits with another indi-

247. KY. REV. STAT. § 334.120(2)(h) (Supp. 1976).

248. CAL. BUS. & PROF. CODE 651.4 (West 1974). *But see* Virginia State Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

249. The statutes obviously do not bar true presentation of technological developments, as to which *see* ELDERLY, *supra* note 4, at 42-45, 49-52.

250. FLA. STAT. ANN. § 468.139(9), (10), (14) (West Supp. 1977). *See also* IOWA CODE ANN. § 154A.24(n)-(q) (West Supp. 1977); 16 C.F.R. 214.7, .9 (1977).

251. LA. REV. STAT. ANN. § 37:2442(5)(u) (West 1974). A Customs Court judge has even taken judicial notice that hearing aids do not cure deafness: *See* J.E. Bernard & Co. v. United States, 262 F. Supp. 434 (Cust. Ct. 1967).

252. KY. REV. STAT. § 334.130(6) (Supp. 1976).

253. For an account of the struggle to obtain the VA test results under the Freedom of Information Act, *see* Consumer's Union v. Veterans' Administration, 301 F. Supp. 796 (S.D.N.Y. 1969), *appeal dismissed as moot*, 436 F.2d 1363 (2d Cir. 1971). *See also* CONSUMER REPORTS 192-93 (April 1971); BERGER, *supra* note 2, at 133-34.

254. ARIZ. REV. STAT. § 36-1901(7)(i) to (m), (p) (1974). *See also* S.D. COMPILED LAWS ANN. § 36-24-39(9) to (16) (1972); 16 C.F.R. § 214.16-.18 (1977).

255. *See, e.g.,* ALA. CODE tit. 46, § 150(32)(B)(3)(j) (Supp. 1974).

vidual who aids in solicitation.<sup>256</sup> New York deems it unethical conduct to grossly overcharge.<sup>257</sup> Tennessee's provision barring the sharing of profits with an individual who is not licensed<sup>258</sup> raises the question of a licensee who is employed by a corporation and who is paid a salary, for example a dealer who works for a department store. Certainly the provision permitting the corporation to hire the dealer also should be interpreted to permit the corporation to share profits with that dealer.

Finally, many of the statutes have unique provisions concerning unethical acts. The Alabama statute declares it unethical to improperly imply a relationship with a manufacturer.<sup>259</sup> A California dealer may not sell hearing aids without maintaining an established business address regularly and routinely open for service to clients.<sup>260</sup> Most states view it as unethical, if not illegal, for the dealer to practice while having a contagious or infectious disease.<sup>261</sup> It is considered unethical for a Florida dealer to fail to properly accept responsibility for a trainee.<sup>262</sup> The Texas law deems it unethical not to engage actively in fitting and dispensing for three years.<sup>263</sup> Taken as a whole, the list of unethical acts is comprehensive, but unfortunately the majority of states merely have incorporated general ethical provisions which do not reach the abuses in the hearing aid industry. Either by regulation or statute, the majority of states need to follow the lead of Arizona, Florida, Kentucky and similar states which have chosen to regulate unethical practices closely.

### *The Disciplinary Mechanism*

A number of states have provided simply that the hearing aid statutes shall be enforced, as with similar boards or agencies, under a uniform licensing enforcement provision.<sup>264</sup> Statutes that do have their own enforcement provisions customarily provide that a written

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256. ARIZ. REV. STAT. § 36-1901(7)(r) (1974).

257. N.Y. GEN. BUS. LAW 783(i)(e) (McKinney Supp. 1976). On the controversial subject of hearing aid prices, see ELDERLY, *supra* note 4, at 23-26, 66-68.

258. TENN. CODE ANN. § 63-1502(5)(r) (1976).

259. ALA. CODE tit. 46, § 150(32)(B)(3)(i) (Supp. 1974).

260. CAL. BUS. & PROF. CODE § 3429 (West 1974).

261. See, e.g., GA. CODE ANN. § 84-5616(l) (1975).

262. FLA. STAT. ANN. § 468.130(8) (West Supp. 1976).

263. TEX. REV. CIV. STAT. ANN. art. 4566-1.10(24) (Vernon 1976). This approach is less effective than the approach taken in states which require proof of continued professional education before a license is renewed.

264. See, e.g., OKLA. STAT. ANN. tit. 59, § 1566(A) (West Supp. 1976).



complaint must be filed within one year of the alleged improper act.<sup>265</sup>

After the complaint is filed, prosecution and investigation in some states is handled by the independent board of hearing aid dealers.<sup>266</sup> If the board itself handles the disciplinary procedure, there is the danger that the accused dealer may be faced with institutional bias. On the other hand, there is also the danger that the board may be lenient toward its own professionals and overlook ethical violations.<sup>267</sup> In some states, the board of hearing aid dealers makes the initial investigation, but the actual prosecution is pursued by the state board of health.<sup>268</sup> In other states, the entire prosecution is handled by the state board of health.<sup>269</sup> Finally, several state statutes provide that enforcement shall be carried out by the local prosecuting attorney or by the state attorney general.<sup>270</sup> Regardless of which authority ultimately prosecutes the case, the hearing customarily honors the rights to confrontation, production of witnesses and use of depositions and subpoenas.<sup>271</sup> An individual who receives an adverse administrative ruling may appeal to a judicial body for review.

There could be a risk in allowing a number of different agencies to become involved. For example, if the board of health issues licenses, but the attorney general has the authority to enforce the act, a lack of cooperation between agencies may hamper enforcement and prevent consistency in the law. In addition, there is certainly an advantage in taking enforcement out of the hands of a part-time board of hearing aid dealers which is comprised in large part of other hearing aid dealers. Enforcement is likely to be more effective if there are full-time staff members and if the disciplinary procedures are well publicized.<sup>272</sup>

Despite the statutory procedure, the evidence of effective enforcement is debatable, even in states with strong statutes.<sup>273</sup> From 1970 to 1974, 2,383 complaints were registered with the state boards. Most

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265. See, e.g., DEL. CODE tit. 16, § 2018 (1975).

266. See, e.g., HAW. REV. STAT. § 451A-15 (Supp. 1975).

267. See MCCORMACK, *supra* note 48, at 1278-82.

268. See, e.g., IND. CODE ANN. § 25-20-1(16) to (20) (Burns 1974).

269. See, e.g., S.C. CODE § 40-25-160 (1977).

270. See, e.g., N.D. CENT. CODE § 43-33-01(1) (Supp. 1977); VT. STAT. ANN., tit. 9, § 2461a (Supp. 1977).

271. See, e.g., HAW. REV. STAT. 451A-15, 16 (Supp. 1975); MICH. COMP. LAWS ANN. § 338.1462 (1976). On the constitutional and statutory requirements for license revocation, see generally COOPER, *supra* note 84, at 144-51, 491-500.

272. STAFF STUDY, *supra* note 1, at 10.

273. The problems of enforcement in Kentucky are reviewed in STAFF STUDY, *supra* note 1, at 27-34; INVESTIGATIONS, *supra* note 3, at 118-27.

of the complaints involved dealer incompetence, unethical practices and breach of warranty claims. Only one hundred and twenty-six individuals had their licenses revoked or suspended and sixteen criminal prosecutions were initiated.<sup>274</sup>

Effective enforcement can be threatened by the lack of governmental cooperation. For example, a dealer in Daytona Beach, Florida<sup>275</sup> had his license suspended for sixty days in July 1974, pursuant to a consent order from the Florida Department of Health. In February, 1975, the Department permanently revoked his license for unethical acts. But the following month a trial judge stayed revocation and permitted the dealer to remain in business. The Department of Health attempted an interlocutory appeal, which was rejected in July, 1975.<sup>276</sup> On remand, a change of venue was granted which was then ruled improper in May, 1976.<sup>277</sup> During this period, the dealer continued to sell hearing aids, despite continued evidence of deceptive and unfair trade practices and despite an action brought by the State's Attorney under the Florida Consumer Protection Act.<sup>278</sup>

If such difficulties in consistent enforcement are widespread, then even the strongest statutes will not protect the hard of hearing adequately. Indeed, an unenforced strong statute may be more damaging to the public than no statute at all, for in the latter instance the customer does not even expect the help of the state.

### *Penalties*

The penalties set forth in the statutes distinguish between unlawful and unethical acts. For example, the South Dakota statute clearly points out, as do most of the other statutes, that unethical conduct is not the basis for criminal prosecution unless it is otherwise declared unlawful.<sup>279</sup> Nearly all of the statutes hold unlawful acts to be misdemeanors,<sup>280</sup> usually of the second degree,<sup>281</sup> which exact a fine

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274. *Id.* at 60-61. See the industry's response in INVESTIGATIONS, *supra* note 3, at 205-09.

275. Florida is reputed to have one of the more effective and active enforcement agencies. INVESTIGATIONS, *supra* note 3, at 127-33.

276. Department of Health and Rehabilitative Services v. Walters, 315 So.2d 494 (1st Dist. Ct. App. Fla. 1975).

277. Walters v. State Department of Health and Rehabilitative Services, 332 So.2d 684 (1st Dist. Ct. App. Fla. 1976).

278. INVESTIGATIONS, *supra* note 3, at 48-53.

279. S.D. COMPILED LAWS ANN. § 36-24-39 (1977).

280. See, e.g., FLA. STAT. ANN. 468.138 (West Supp. 1977).

281. *Id.*

ranging from \$100<sup>282</sup> to \$1,000<sup>283</sup> and imprisonment for ten days<sup>284</sup> to one year.<sup>285</sup>

All of the statutes have provisions for suspension or revocation of a hearing aid dealer's license.<sup>286</sup> Some states place a time limit on the suspension, typically six months.<sup>287</sup> Approximately half of the states give the hearing aid board or the state board of health the power to seek injunctive relief<sup>288</sup> against an illegal or unethical practice. Kentucky provides that a statutory injunction may be granted even without a showing that any person has been damaged or has sustained a loss.<sup>289</sup> Delaware provides that the board may seek an injunction even though it also seeks a fine or imprisonment.<sup>290</sup> In contrast to the Delaware approach, South Dakota considers the injunction an alternative to criminal proceedings.<sup>291</sup> This statutory approach fails to provide for both the protection of the public in the future and the punishment of the offender for past actions.

Nevada provides for additional penalties. The state statute provides for a possible probationary period of up to six months and gives the board the power to issue either public or private reprimands to a dealer who violates the statute.<sup>292</sup> Only New Jersey specifically has included the remedy of restitution.<sup>293</sup> It is unfortunate that the legislatures have not granted more boards the power to seek injunctive relief and damages for violations of the state acts.

### CONCLUSION

As the preamble to the Florida statute<sup>294</sup> indicates, the purpose of hearing aid statutes is to protect the hard of hearing. But many of the

282. See, e.g., S.C. CODE § 40-25-190 (1977).

283. See, e.g., N.Y. GEN. BUS. LAW § 784(10) (McKinney Supp. 1976).

284. See, e.g., OKLA. STAT. ANN. tit. 59, § 1568 (West Supp. 1976).

285. See, e.g., MICH. COMP. LAWS ANN. § 338.1464 (1976).

286. See, e.g., COLO. REV. STAT. § 12-65-114 (Supp. 1976).

287. See, e.g., S.D. COMPILED LAWS ANN. § 36-24-40 (1977).

288. See, e.g., ARK. STAT. ANN. § 72-1716 (Supp. 1975); N.J. STAT. ANN. § 45:9A-20 (West Supp. 1977).

289. KY. REV. STAT. § 334.990(2) (Supp. 1976).

290. DEL. CODE tit. 16, § 2017(b) (1975).

291. S.D. COMPILED LAWS ANN. § 36-24-42 (1977). Under the South Dakota law, the Board is barred from bringing criminal action when it seeks injunctive relief.

292. NEV. REV. STAT. § 637A.290 (1975). See also N.C. GEN. STAT. § 93D-13(a) (1975) (private reprimand).

293. N.J. STAT. ANN. § 45:9A-19 (West Supp. 1977). Pennsylvania permits "any buyer" injured by a violation of the act to recover treble damages and attorney's fees. PA. STAT. ANN. tit. 35, § 6700-608 (Purdon Supp. 1977). But the buyer must initiate the action himself, rather than have the board pursue it.

294. FLA. STAT. ANN. § 468.121 (West Supp. 1977).

statutes do not accomplish that desired goal. Too many of the statutes have the traditional flaws of regulatory agencies: a board dominated by members of the industry, inadequate funding, gaps in the regulatory scheme, vague and general standards, and ineffective or nonexistent enforcement. A handful of states, including Colorado, Florida, Iowa, Kentucky and Maine, have amended the traditional approach with specific provisions more appropriate to the problems. These states have required continuing education, mandatory medical referral, unlimited right of rescission, and specific advertising restriction. Yet the broad provisions of these statutes also must be enforced, and the evidence on this count is not convincing.

To adopt the approach of Minnesota and New York, which require medical approval and recommendation before a hearing aid is sold by any individual, licensed or not, may be the easiest type of statute to enforce. But it also might doom the hearing aid dealer's future occupation. Despite some abuses and shortcomings, those 15,000 individuals have dispensed to more than three million Americans hearing aids that provide assistance with their handicaps.

In adopting its August 1977 regulation, the FDA emphasized the roles of all members of the hearing health team—the otolaryngologist, the audiologist, the hearing aid dealer—in the task.<sup>295</sup> The adoption of the federal regulations, combined with experience under the various state approaches, should, over time, clarify the roles of the professions and should provide more definite answers to the goal of helping the hard of hearing.

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295. 42. Fed. Reg. 9285, 9287 (1977).

